Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL No 8416

concerning the issue of cremating deceased carriers of radioactive sources

October 2008

1. INTRODUCTION AND ISSUE

In 2003, the Superior Health Council issued an advisory report and recommendations on the dispersion of radioactivity from sources used for medical purposes and carried by deceased patients (SHC 5110/3). In compliance with the recommendations made in this advisory report, the FANC conducted a field study (RASO) to provide a more detailed answer to the questions submitted. On 21 April 2008, the FANC requested the Superior Health Council to assess the results of this study and to check whether some of the recommendations in the previous advisory report needed revising. On 28 May 2008, the FANC submitted an additional request to the SHC in which it put a series of specific questions aimed at clarifying the issue. The SHC's answers can be found in appendix I.

2. ADVICE

- The SHC can but rejoice at the quality of the study (entitled RASO) conducted by the FANC and Controlatom. This long-term research was carried out in a professional, scientific and rigorous manner with the co-operation of the director of the Westlede crematorium and the informed participation of its staff. The SHC finds it particularly important that this study was carried out over a 6-month period under real conditions in one of the largest crematoria of the country and in all transparency towards its staff. In addition, a case study was performed in the Hasselt Crematorium, where the FANC was required to monitor the controlled cremation of a person deceased 5 months after having received Iodine-125 seed implants to treat prostate cancer (brachytherapy). The data presented are precise and exhaustive.

It follows that the SHC takes note of the validity of the data transmitted. In short, it retains the following elements:

1) The prevalence of cases in which a detectable level of radioactivity could be measured is 1:500, with only 2/3 in case of therapeutic applications. At the national level, this concerns some 60 cases a year.
2) In the context of this study, during which the rules of good practice were seen to have been observed, none of the crematorium staff incurred any significant exposure. It should be pointed out that even if the usual protective measures had not been taken in these cases (worst case scenario), the dose received by the workers would still have remained well below the public dose limit;

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3) The SHC finds that the study is based on radioactivity measurements carried out at the coffins and does not take into account the exposure of individuals, be it as a result of exposure that can be looked upon as occupational, or the exposure of members of the public (e.g. relatives of the deceased, those in charge of transporting the body or funeral care);
4) The measurements obtained during the controlled cremation of the deceased carrier of brachytherapy sources indicate that it is entirely possible to carry out this type of procedure, provided that reasonable precautions are taken and the advice of experts in medicine and physics is sought. The latter are in charge of setting up the necessary safety system and carrying out the required radioactivity measurements without delay, both during and after the cremation, in order to ensure staff protection. This observation is in keeping with recommendation 5110/3, which allows cremation under controlled conditions even before the levels of radioactivity have reached the threshold defined in appendix 1 of the advisory report in question.

- The SHC takes the view that the recommendations issued in its previous advisory report provide adequate protection to workers carrying out cremations as well as the population and that there is no need to modify the technical aspects of this guideline. The SHC has recently taken a similar position as regards the specific case of I-125 seed implants in light of international recommendations (ICRP98). A critical review of the scientific literature does not provide sufficient grounds to contradict this.

However, the additional data the SHC now has at its disposal allow it to add a few additional observations to this guideline. They do not affect the previous advisory report substantially.

Even though the results of this study are reassuring, it should be noted that the obligatory notification system is flawed: throughout the course of the study, not a single case was notified (except for the case study involving the patient with I-125 seed implants). This may have an impact not only at the time of cremation but also at any stage between the patient's passing away and his/her transfer to the crematorium. In this respect, no heed has been paid to the general recommendations issued on therapeutic applications by the SHC in its advisory report 5110/3. Improving the notification procedure is therefore the best way to optimise this type of practice.

At present, it is impossible to have access to a centralised database. Such an instrument would eventually allow for problematic cases to be detected rapidly and efficiently, especially in the area of radioprotection.

In order to improve the notification procedure, the Superior Health Council therefore advises the FANC, which is competent for radioprotection, to inform the regulatory authorities in charge of these different matters through the means that it considers appropriate. This especially concerns the regional ministers who are competent for the organisation of funerals, the governors and/or mayors, who are in charge of the administrative acts, the medical profession, and funeral directors and crematoria managers through their professional organisations. In addition, an operational document aimed at the last two needs to be drawn up based on the example in appendix II.

It goes without saying that the first stage of effectively notifying a death is drawing up the confirmation of death. In order to ensure that the medical profession is properly informed, the SHC offers to assist the FANC in setting up an information campaign that would be shaped in a way that they both consider appropriate (e.g. the Medical Association bulletin, general medical press, specialised medical press in the form of an article,...).

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Finally, with respect to this issue, the SHC advises the FANC to suggest to the competent minister to have section C of the death certificate provided in the RD of 17.06.99 modified in order to simplify issues that concern the presence of radioactivity in human remains, thus raising fewer questions among notifying physicians.

The SHC therefore concludes in the light of the data obtained by the FANC that there is no reason to change advisory report 5110/3 substantially. However, the advisory report from 2003 has been amended (cf. appendix III) in order to take into account the recommended measurements that were carried out by the FANC as well as any modifications in the different texts of law.

3. ELABORATION AND ARGUMENTATION

The data provided by the FANC result from 2 field studies. The first, entitled RASO, is an observational study aimed at determining the prevalence of cases in which a detectable level of radioactivity is measured in a crematorium, as well as the type of radioisotope involved. In each identified case, the behaviour of radioactive contaminants was examined and staff exposure as well as contamination of the working environment was measured. On the basis of the results that were obtained under conditions in which the rules of good practice were met, estimates were made as regards the maximum risk (worst case scenario). The second part concerns a case study that was performed in the Hasselt Crematorium, where the FANC was required to monitor the controlled cremation of a person deceased 5 months after having received Iodine-125 seed implants to treat prostate cancer (brachytherapy).

The study carried out by experts in physical control (Controlatom) at the request of the FANC yielded the following results[1]:

1) The prevalence of cremation cases in which measurable levels of radioactivity could be detected taking into account the means used was 6/3338, four of which concerned therapeutic applications. In all of these cases, the measured activity was low, which meant that the levels of staff exposure measured were negligible.
2) Simulations on the basis of a worst case scenario showed that in each of these cases, staff exposure would have remained low and in any case below the legal dose limits.
3) The only case in which a potential radiological risk was identified involved a deceased carrier of sealed brachytherapy sources (I-125) that had been implanted 5 months earlier (case study). Still, with experts from the FANC and Controlatom supervising the cremation, this risk was entirely under control. It is impossible to assess what the radiological impact would have been if no protection or control measures had been taken.

It follows that these data show that, though the risk appears to be very low, as mentioned previously in several studies, it remains justified to exert caution, especially as regards implantable brachytherapy sources that have a long half-life.

There seems to be no justification to change current measures. Indeed, the safety-first principle must be applied in this case in order to take into account the evolution of medical treatments. Adhering to this principle creates a psychological climate that is favourable for the patient's continuing to receive the best treatment possible. The cooperation of the medical profession in managing this risk is of crucial importance, with the doctors in charge of such treatments being in the best position to know and assess the benefits and risks involved.

[1] A technical analysis carried out by experts in physical control and radioprotection can be found in appendix IV

This study also provides reassurance for the directors and staff of crematoria, with the figures obtained showing that these establishments do not need to be classified according to the provisions of the RGPRI[2].

On this point, the SHC confirms its previous advisory report.

The 2003 recommendations allowed for the possibility of carrying out a cremation even before the recommended waiting period had come to an end, provided certain rules were obeyed. The role which the FANC can play in these cases allows for the wishes of the deceased and their relatives to be met properly, whilst providing efficient protection to those involved, the population, and the environment. The SHC insists on the need for the FANC to play a twofold role: on the one hand, it should exert an advisory function in all situations that are brought to its knowledge in which the recommended waiting periods have been satisfied; on the other, it should play an active role in controlling, monitoring and assisting the workers who are involved in cases in which they have not.

For the FANC to fulfil its role in managing this risk, it is of crucial importance that it be informed of these (rare) cases in which potential problems are to be expected.

Efficient notification is a sine qua non condition for the optimal management of these cases. Even though the results of this study are entirely reassuring, it is noteworthy that there had been no notification in any of the cases (n=6) of the RASO study in which a measurable amount of radioactivity had been detected.

It follows that it is necessary to make the different parties involved in the funeral process in a general sense aware of the measures that need to be taken when faced with this issue. This primarily concerns those involved in carrying out the funeral itself, viz. workers in crematoria and funeral services, but also those concerned by the preceding stages.

For this awareness raising to be productive, it is crucial that those involved should be correctly informed of the situation they are faced with. In this respect, it is of key importance that section C of the death certificate be filled in correctly in order for the medical officers appointed by the Registrar of Births, Marriages and Deaths to carry out their duty efficiently.

In chronological order, it is therefore essential that the physician who confirms the death and fills in the notification provided by the RD of 17.06.99 be as well informed as possible about the potential presence of radioactive sources (sealed or unsealed) in the body. This can be done in a simple manner without prejudice to the terms of the Acts on the protection of privacy and patient rights, by providing the patients (whose consent is required) with a document or identification card that defines the qualitative and quantitative risk to third parties, both in terms of intensity and duration. Recordings of any type in a database (no matter how secure) seem to be entirely illusory at present, though this would be a simple and effective way to improve the notification.

Second, it is necessary to strengthen the role of the medical officers or medical referees appointed by the Registrar of Births, Marriages and Deaths[3] (as well as the potential future role of specialists

[2] Arrêté royal du 20 juillet 2001 portant règlement général de la protection de la population, des travailleurs et de l'environnement contre le danger des rayonnements ionisants (Royal Decree of 20 July 2001 establishing the general regulations aimed at protecting the population, workers and environment against the danger of ionising radiation).

[3] Replacing the role previously played by the federal sanitary health inspectors.

in forensic medicine) in this matter. Indeed, they are the ones who can mediate between the family and attending physician of the one hand, and the administration in charge of issuing the authorization for burial or cremation on the other. They are also the ones who, as a result of medical confidentiality as well as their duty to implement the Law in the interest of the population, are in the best position to require the expertise and logistical support of the Federal Agency for Nuclear Control that will enable them to resolve these sometimes complex situations.

As there can be no question of defining a unique and fixed framework, the competent authorities need to rapidly inform those in charge of carrying out the cremation or burial of the measures that are to be taken in each individual case, following Section 69[4] of the RD of 20 July 2001. The latter will then be able to implement the ad hoc guidelines. Ideally, these guidelines should be notified as quickly as possible to those close to the deceased or in charge of them.

On the basis of the collected data, the SHC also expresses its opinion on the following technical points:

1) The SHC recommendations strongly advise that the ashes should be buried. If not, it should be mandatory for the ashes to be kept in the crematorium under the conditions specified by the FANC. Incidentally, it is worth recalling that if contaminated ashes were to be moved, their transportation would be subjected to the legislation on the carriage of dangerous substances (ADR), making it inadvisable to do so.
2) The combined use of dust filters and activated carbon can reduce the dispersion of radioisotopes in the environment. However, care should be taken that these materials are not stored near the workers after use.
3) The SHC repeats the general precaution instructions and advises against thanatopraxy. Embalming is no longer authorised except in exceptional circumstances.
4) Finally, organ removal may be considered if precautionary measures are taken for those involved in the procedure and if the organ that is to be removed is not the main source of radioactivity.

4. REFERENCES

SHC – Superior Health Council (Belgium). Avis et recommandation du Conseil Supérieur d'Hygiène concernant la dispersion de radioactivité en provenance de sources utilisées à des fins médicales portées par des patients décédés – SHC 5110/3 ; 2003.
ICRP 98
Cremation after prostate implantation of seeds containing I-125
Systematic detection of radioactive corpse & monitoring of their cremation
Royaume de Belgique. AR du 17 juin 1999 prescrivant l'établissement d'une statistique annuelle des causes de décès. MB du 4 septembre 1999. p 32949-32971.
Proposition de modification de l'Art. 69 du RGPRI du 20 juillet 2001.

5. APPENDIXES

1/ Updated version of advisory report 5110/3

[4] In this respect, the SHC wishes to refer to Section 69, which is soon to be amended. As a matter of fact, this amendment was the subject of an advisory report (8427) issued by the SHC, which strengthened the prerogatives of the FANC in this matter.

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6. COMPOSITION OF THE WORKING GROUP

All experts joined the working group in a private capacity. The names of the members and experts of the Superior Health Council are indicated with an asterisk*.

The following experts took part in drawing up the advisory report:

Caussin Jacques*	(Physical control, UCL) (Rapporteur)
Covens Peter *	(Radioprotection, physical control, VUB)
Eggermont Gilbert*	(Radioprotection,VUB)
Jamar François*	(Nuclear medicine, UCL)
Pirlet Véra	(Radioprotection, physical control, ULg)
Poelaert Marc	(Physical control, UCL)
Surinx Lydia	(Funeral practice, Hasselt Crematorium)
Van Marcke Hans*	(Radioecology, SCK-CEN)
Van Eijkeren Marc*	(Radiotherapy, oncology, UGent)
Wambersie André*	(Radioprotection, industrial medical officer)

The following experts were heard:

Coenegrachts Kris	(Funeral practice, Director of the Westlede Crematorium, Lochristi)
Van Cauteren Jef	(Physical control, Controlatom)

The Administration was represented by :

Lefebvre Guy	(FANC)
Van Bladel Lodewijk	(FANC)

The working group was chaired by François Jamar, the scientific secretary was Eric Jadoul.

Advisory report and recommendations of the Superior Health Council
Amended version, September 2008

Preliminary observations - The Superior Health Council's advice was requested on the dispersion of radioactivity from sources used for medical purposes and carried by deceased patients. This means that all useful measures aimed at avoiding the contamination and external irradiation of those involved (family, hospital staff, workers in funeral services and crematoria,...) need to be taken. In order to manage this issue, it is necessary to ensure that optimal controls are carried out on human remains that constitute "radioactive sources" on the one hand, and to provide relevant and reasonable information to those involved in the different practices concerned (post-mortem, funeral, embalming, anatomy, cremation, etc...) on the other. In its analysis, the Superior Health Council considers not only the protection of the population and the environment, but also the ethical issues that can be raised in such circumstances.

In its request of 14 May 2003, the Federal Agency for Nuclear Control asks for advice on the overall approach to be taken after the passing away of patients who have received radioactive substances, especially as regards the issue of cremation. This request was submitted in the context of the ongoing revision of Section 69 of the Royal Decree of 20 July 2001, which establishes the general regulations aimed at protecting the population, workers and environment against the danger of ionising radiation. In this document, which is mainly concerned with the issue of cremation, the Superior Health Council provides the following advice and recommendations:

- In the case of patients deceased after having been administered **diagnostic radiopharmaceuticals,** all funeral-related practices, including cremating the body, are authorised without restriction.

- If the physician drawing up the death certificate is aware that the deceased had recently received **therapeutic radiopharmaceuticals (including for palliative purposes)**, he/she will mention this in the box provided on the form. The Registrar of Births, Marriages and Deaths will then require the advice of the medical officer, who will contact the attending physician(s) and the FANC. They will provide information on any potential radioactive contamination hazard, as well as its nature. These proceedings aim at drawing the attention of the funeral services concerned and allowing them to take appropriate protective measures in time, both as regards internal radioactive contamination (wearing a mask and gloves) and external irradiation. They also aim at ensuring that the deceased's relatives are protected as quickly as possible through the following measures: in the death chamber, one should keep an adequate distance from the deceased, pregnant women and small children are advised to stay away or only to remain in the room for a brief period of time; there should be limited handling of the corpse; precautions should be taken as regards the internal contamination hazard, especially with respect to the handling of contaminated objects.

- As regards persons deceased after having been administered **therapeutic** radiopharmaceuticals (including for palliative indications), cremating the body is authorised:

  - Without restriction if the A_c activity of the radionuclide under consideration does not exceed that mentioned in appendix 1, column 4. This is assumed to be the case if the time that has passed between the moment at which the treatment was administered and that at which the patient died corresponds to or exceeds the time interval mentioned in appendix 1 (column 5).

  - Within this time interval, the Superior Health Council takes the view that the body should be buried. However, if it is the deceased's and/or their family's express wish to have the remains cremated, the following precautions need to be taken:
    - Crematorium staff should wear a mask (ideally one with P3 filtration efficiency) and waterproof gloves;
    - The urn containing the ashes can be buried immediately. The ashes may not be scattered or released to the family within the time interval mentioned above for the radionuclide in question (appendix I, column 5). The latter begins on the day the radiopharmaceutical was administered. The Superior Health Council advises to wait until this radionuclide has decayed away almost entirely before scattering the ashes or returning the urn to the family;
    - Particular care should be taken to prevent dispersion of the ashes in the installation;
    - In a general sense, the cremation can only be carried out if the provisions concerning worker protection and the inspection of the premises are met (RD 20 July 2001).

- As regards patients deceased **in hospital** after having received **therapeutic radiopharmaceuticals**, no human remains will be released from the hospital before the dose rate at one metre is 20 µGy/h or less, i.e. that which was set for patient release by the joint working group of the Superior Health Council (radiation department) and the Medical Board of the Special Committee (*Recommandations du 16 mai 1997 relatives aux conditions et aux critères d'hospitalisation et de sortie des patients traités au moyen de radionucléides par voie métabolique, confirmées en 2005 par l'avis 7221/2*) (i.e. Recommendations of 16 May 1997 concerning the conditions and criteria for the hospitalization and release of patients receiving metabolic radionuclide therapy, confirmed in 2005 through advisory report 7221/2). Protective measures will be taken before and after the remains are released in order to protect the family, hospital workers and the staff of funeral services (depending on the radionuclide concerned: wearing gloves for any direct handling of the human remains, storing the remains in an appropriate place, ensuring that an adequate distance is maintained, e.g. by setting up a barrier with flowers around the coffin in the death chamber, keeping pregnant women and small children away or limiting the duration of their presence, …)

- As regards patients who have passed away within the time interval referred to in appendix 1, column 5, after having received therapeutic radiopharmaceuticals, embalming is prohibited.

- In order for appropriate precautionary measures to be taken *immediately* in case the deceased passed away **at home** after having received therapeutic radiopharmaceuticals, including for palliative indications, the *instruction leaflet* the physician provided to the patient will contain a section with the general rules of conduct that initially need to be followed by the family and healthcare workers, unless otherwise specified (according to the radionuclide concerned: see above). The instruction leaflet will also mention the name and contact number of the attending physician, which will enable the physician who draws up the death certificate to contact the latter without delay in order to obtain instructions that are more precise and more appropriate to the actual situation and hand them over to those in charge of taking care of the remains.

In addition, the Superior Health Council advises that an information campaign be conducted on this issue. It should target the following:

- Specialists who are licensed to possess and use radioactive substances in accordance with the terms of Sections 53.3.8 and 53.4 of the Royal Decree of 20 July 2001, with particular emphasis on the recommendation made in the previous paragraph;
- Company doctors licensed according to the terms of Section 75 of the RD mentioned above;
- Federal sanitary health inspectors;
- Medical officers appointed by the Registrar of Births, Marriages and Deaths;
- Crematoria throughout the country;
- Funeral directors, those in charge of transporting the remains and cemetery workers;
- The medical profession, especially the Heads of healthcare establishments and general practitioners;
- Approved organisations and physical control departments.

Moreover, the Superior Health Council advises that when either sealed (brachytherapy) or unsealed new therapeutic radiopharmaceuticals are introduced, the Federal Agency for Nuclear Control draw up the procedure that needs to be implemented if the patient passes away, in accordance with the recommendations issued above.

Considering the scarcity of available data in 2003, the Superior Health Council advised the Federal Agency for Nuclear Control to set up an evaluation programme of the actual impact on the population, the environment and workers in crematoria and funeral homes as regards the radioactive contamination of human remains. This programme needs to take into account both the internal contamination and external irradiation hazards. Particular attention should be paid to iodine radioisotopes. The Superior Health Council was informed about the results of such studies in May 2008. In the light of this information, it confirmed its initial advisory report.

Appendix 1

Time interval between treatment administration and the death of the patient during which special measures need to be taken for the remains to be cremated*

Radionuclide (1)	Indication (2)	Standard activity A_t (MBq)[1] (3)	Max. activity at the time of cremation A_c (MBq) (4)	Precautionary period (days)[2] (5)
Sm-153	Bone metastases	2960	1	**13**
Y-90	Zevalin®	1110	0,1	**15**
I-131	Thyroid cancer (min)	3700	1	**16**
I-131	Thyroid cancer (max)	7400	1	**18**
I-131	Thyroid: benign disease (min)	370	1	**27**
I-131	Thyroid: benign disease (max)	555	1	**29**
Y-90	Synoviorthesis	185	0,1	**29**
I-131	MIBG (min)	1800	1	**39**
I-131	MIBG (max)	7400	1	**47**
P-32	Vaquez	185	0,1	**50**
I-131	Lipiodol	2220	1	**57**
Pd-103	Prostate	4440	100	**93**
Sr-89	Bone metastases	148	1	**303**
I-125	Prostate	1480	1	**632**

[1] If the activity exceeds the standard activity by more than 20%, the precautionary period should be recalculated by the specialist in nuclear medicine or radiotherapy in consultation with the licensed organisation or physical control expert.

[2] Should the patient die very early (taking into account the time interval mentioned in column 5), the precautionary period should be recalculated by the specialist in nuclear medicine or radiotherapy in consultation with the licensed organisation or physical control expert.

*The values mentioned in this table may be rounded off for practical purposes.