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Considerations for the release of patients after radionuclide therapy

Technical report

The Radiation Safety Authorities in Denmark, Finland, Iceland, Norway and Sweden

Considerations for the release of patients after radionuclide therapy

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Authors: Søren Albrecht Lassen, Tina Hybertz Andersen, Jukka Liukkonen, Nellý Pétursdóttir, Annette Andersen and Lars Ideström

Approved by the Nordic Working Group on Medical Applications, in 2023 consisting of:
Hanne N. Waltenburg (Denmark), Jukka Liukkonen (Finland), Ritva Bly (Finland), Petra Tenkanen Rautakoski (Finland), Edda Lina Gunnarsdóttir (Iceland), Nellý Pétursdóttir (Iceland), Jónína Guðjónsdóttir (Iceland), Eva G. Friberg (Norway), Anders Widmark (Norway), Torsten Cederlund (Sweden), Carl Bladh (Sweden) and Anja Almén (Sweden)

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Summary

The purpose of this document is to describe the considerations necessary for hospitals and national regulatory authorities in the Nordic countries, in order to establish and evaluate the criteria for release of patients after radionuclide therapy.

The release of patients should be based on a safety assessment where the exposure to members of the public and persons in close contact with the patient is evaluated. Exposure scenarios should, among other things, consider the patient's individual domestic situation, working life and possibilities for handling of radioactive waste. The workers at the nuclear medicine department are expected to receive training for occupational protection and their occupational exposures to be under surveillance. Therefore, occupational protection is out of the scope of this document. The document takes into account the different regulatory approaches and practices in the Nordic countries regarding the groups carers and comforters versus members of the public. The concept of dose constraints is widely incorporated by the national regulatory authorities and is considered a useful tool for assessing doses to relevant persons.

Resumé

Formålet med dette dokument er at beskrive de overvejelser, som hospitaler og de Nordiske strålebeskyttelsesmyndigheder skal gøre for at kunne fastsætte og evaluere kriterier for udskrivning af patienter efter behandling med radioaktive lægemidler.

Kriterier for udskrivning af patienter bør baseres på en sikkerhedsvurdering, hvor stråleudsættelsen af enkeltpersoner i befolkningen og personer i tæt kontakt med patienten evalueres. Scenarierne for stråleudsættelsen bør bl.a. tage udgangspunkt i patientens individuelle situation i hjemmet, patientens arbejdsliv samt mulighederne for håndtering af det radioaktive affald. Arbejdstagerne på den nuklearmedicinske afdeling forventes at være uddannet i strålebeskyttelse i forhold til deres stråleudsættelse i forbindelse med arbejdet, og deres stråleudsættelse skal overvåges. Strålebeskyttelse af arbejdstagerne er derfor ikke omfattet af dette dokument. Dokumentet tager hensyn til de nordiske landes forskellige lovgivningsmæssige tilgange og praksis for personkategorierne omsorgspersoner og hjælpere samt enkeltpersoner i befolkningen. Begrebet dosisbinding anvendes bredt af de nationale strålebeskyttelsesmyndigheder og anses for at være et nyttigt redskab til evaluering af doser til relevante personer.

Yhteenveto

Tämän julkaisun tarkoituksena on esittää tarpeelliset näkökohdat pohjoismaisille sairaaloille ja kansallisille viranomaisille isotooppihoidon saaneiden potilaiden kotiuttamista koskevaan arviointiin.

Potilaiden kotiuttamisen tulisi perustua arvioon väestön ja potilaan kanssa läheisessä kontaktissa olevien henkilöiden altistuksesta. Altistumisskenaarioissa olisi muun muassa otettava huomioon potilaan yksilöllinen tilanne kotona, työelämässä ja radioaktiivisen jätteen käsittelymahdollisuudet. Isotooppiyksiköiden työntekijöiden odotetaan saavan koulutusta työsuojelusta ja heidän työperäistä altistumistaan on seurattava. Sen vuoksi työperäiseltä altistukselta suojelu ei kuulu tämän julkaisun piiriin. Julkaisussa otetaan huomioon Pohjoismaiden erilaiset lainsäädännölliset lähestymistavat ja käytännöt, jotka koskevat tukihenkilöitä ja väestöä. Kansalliset viranomaiset ovat ottaneet annosrajoitusten käsitteen laajalti käyttöön, ja sitä pidetään hyödyllisenä välineenä arvioitaessa asianomaisille henkilöille aiheutuvia altistuksia.

Ágrip

Tilgangur þessa rits er að lýsa þeim atriðum sem nauðsynlegt er að sjúkrahús og stjórnvöld á norðurlöndunum taki tillit til þegar viðmið eru sett um útskrift sjúklinga eftir meðferð með geislavirkum efnum.

Útskrift sjúklinga ætti að byggjast á öryggismati þar sem geislun á almenning og einstaklinga í nánu sambandi við sjúklinginn er metin. Meðal annars ætti að taka tillit til einstaklingsbundinna heimilisaðstæðna, starfsaðstæðna og mögulegrar meðhöndlunar á geislavirkum úrgangi. Gert er ráð fyrir að viðkomandi starfsmenn sjúkrahúss fái þjálfun í geislavörnum starfsmanna og að fylgst sé með geislaálagi þeirra í starfi. Þess vegna er ekki fjallað um geislavarnir starfmanna í þessu riti. Tekið er mið af mismunandi regluverki og starfsháttum á Norðurlöndunum, varðandi umönnunaraðila annarsvegar og almenning hinsvegar. Hugtakið geislahömlur hefur víða verið tekið upp í löggjöf og er talið gagnlegt við mat á geislaskömmtum þeirra einstaklinga sem hér um ræðir.

Sammendrag

Hensikten med denne veilederen er å beskrive de hensyn som sykehusene og nasjonale myndigheter i de nordiske landene må ta i betraktning, ved etablering og evaluering av kriterier for hjemsendelse av pasienter etter nukleærmedisinsk behandling.

Hjemsendelse av pasienter bør baseres på en risikovurdering, der eksponering til allmennheten og personer i nærkontakt med pasienten, vurderes. Scenarier for eksponering som bør vurderes, er blant annet boforhold, arbeidsforhold og muligheter for å håndtere radioaktivt avfall. Det forventes at yrkeseksponerte ansatte ved en nukleærmedisinsk avdeling får tilstrekkelig opplæring i strålevern relatert til sine arbeidsoppgaver, og at deres stråledoser overvåkes. Yrkeseksponering er derfor ikke en del av denne veilederen. Veilederen tar hensyn til de ulike regelverkene i de nordiske landene angående gruppene kalt omsorgsytere (carers and comforters) og allmennhet. Konseptet «doseføringer» (dose constraints) er innarbeidet praksis i de nordiske landene og anses som et nyttig verktøy i vurderingen av stråledoser til relevante personer.

Sammanfattning

Syftet med detta dokument är att beskriva de överväganden som krävs för sjukhus och nationella strålskyddsmyndigheter i de nordiska länderna, för att fastställa och utvärdera kriterierna för när patienter kan lämna sjukhuset efter nuklearmedicinsk behandling.

Huruvida patienten kan lämna sjukhuset bör baseras på en strålsäkerhetsbedömning där exponering av allmänheten och personer i nära kontakt med patienten utvärderas. Exponeringsscenarier bör bland annat beakta patientens individuella hemsituation, arbetsliv och möjligheter att hantera radioaktivt avfall. Arbetstagarna på det behandlande sjukhuset förutsätts få utbildning i strålskydd och deras stråldoser övervakas. Strålskyddet för arbetstagare på sjukhuset omfattas därför inte av detta dokument. Dokumentet tar hänsyn till de olika regelverken i de nordiska länderna när det gäller grupperna vårdande och stödjande samt personer ur allmänheten. Konceptet med dosrestriktioner tillämpas av de nationella strålskyddsmyndigheterna och anses vara ett användbart verktyg för att bedöma doser till relevanta personer.

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Introduction

In the Nordic countries, an increasing number of patients undergo radionuclide therapy. In addition, new radionuclide therapies and new radiopharmaceuticals are continuously being introduced. Release of patients following such therapies prompts consideration of several aspects regarding radiation protection, in particular related to potential exposures of persons in close contact with the patient, e.g. family members, home nurses, chauffeurs and co-workers. The exposure pathways for each of these groups vary according to the particular circumstances related to individual patients and may include both external and internal exposure. Issues related to management of radioactive waste may play a significant role in this regard. Consequently, recommendations addressing radiation protection should also consider the effects of contamination and arrangements for management of radioactive waste.

Release of patients after radionuclide therapy has been addressed by international radiation protection organizations, national regulatory authorities and the European Commission, and a selection of publications from these organizations are listed as references in this document. Even though some of the publications address specific radionuclide therapies, e.g. I-131, the underlying general considerations may also apply to other types of therapies.

In the Nordic countries, different regulatory approaches and practices exist for release of patients after radionuclide therapy. The purpose of this document is to summarize experiences and identify areas where practical guidance and specific recommendations on this topic may be of relevance in all Nordic countries. In the following sections, the overall topics and contents to be addressed in such guidance are described.

A treatment should only be carried out if properly justified, and while the medical benefit for the patient is a primary factor in the justification, it is not the only aspect to be taken into consideration. The potential impact of the ionizing radiation on persons in close contact with the patient as well as on members of the public and the environment must also be taken into account, in particular as a part of the considerations concerning the release of the patient from the hospital. Therefore, release of patients should always be evaluated and managed on an individual basis, while the methodology and the general considerations pertaining to release of patients should be treated as part of an appropriate safety assessment.

For therapies involving radionuclides not previously used, there could be new scenarios that would need to be considered. This, of course, will need to be described in an updated safety assessment prior to implementation of the new therapies.

The general methodologies and conclusions in this document should be taken into account when considering release of patients and when developing the safety assessment for any radionuclide therapy.

The concept of dose constraints and carers and comforters

The use of dose constraints for carers and comforters and members of the public is recommended by ICRP and required in the Council Directive 2013/59/Euratom (EU-BSS) (1).

Dose constraints

Dose constraints are values directed towards an activity as a benchmark for optimisation of protection and safety. Dose constraints are fundamentally different from dose limits that according to the ICRP 103 (2) are defined as "The value of absorbed, equivalent, or effective dose that is applied to exposure of individuals in order to prevent the occurrence of radiation-induced tissue reactions or to limit the probability of radiation-related stochastic effects to an acceptable level. Dose limits apply to exposures from regulated sources only; it does not apply to medical and environmental exposure."

Dose constraint	Dose limit
A constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation.	The value of the effective dose (where applicable, committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual.

***Table 1**. Dose constraints and dose limits as described in the EU-BSS.*

Dose constraints are

- source related, i.e. apply to exposure from a given source,
- prospective, i.e. to be used for planning purposes, and
- a value defined for the purpose of optimization of radiation protection.

Dose constraints should be applied to the radiation source, as opposed to dose limits that apply to the exposure to the exposed person from all sources.

The general concept of applying dose constraints for medical use of radiation is also described in chapter 3 in the EC RP97 (3).

Carers and comforters

IAEA defines carers and comforters as persons who, outside an occupational capacity, willingly and voluntarily help in the care, support and comfort of a patient undergoing a medical procedure involving ionizing radiation. There might be others, e.g. family members, that are only occasionally exposed, and they would therefore be regarded as members of the public.
It may be justified that carers and comforters receive higher doses than members of the public and consequently a dose constraint higher than the dose limit for members of the public can be defined.
IAEA defines members of the public as persons who are considered neither occupationally exposed nor carers and comforters.

Basic radiation exposure principles/exposure pathways

For medical use of radiation, in general three types of exposures are considered: occupational exposure, medical exposure (exposure of the patient as well as of carers and comforters), and public exposure.

In assessing the exposure relevant for the release of patients, the relevant modes of exposure (internal and/or external) as well as the physical and biological decay properties of the radionuclides play an important role.

Due to the short range/low penetrating power of alpha radiation, the most significant mode of exposure to consider for alpha-emitting radionuclides is internal exposure, which may occur as a result of inhalation, ingestion or absorption through the skin, via wounds, abrasions etc.

Beta-emitting radionuclides are relevant to consider for external exposure at short distances, especially in case of contamination of the skin. In addition, beta-emitters may result in exposure through inhalation, ingestion, or absorption through the skin, via wounds, abrasions etc.

Due to the penetrating nature of gamma-radiation, gamma-emitting radionuclides play a significant role in assessment of external exposure, either from a distance or through contamination of the skin. Internal exposure may result from inhalation, ingestion, or absorption through the skin, via wounds, abrasions etc.

Exposure pathways can be both external and internal.

External exposure

For beta and gamma emitters the most important factors affecting the radiation exposure are:

- Decay properties of the radionuclide used
- Activity amount administered to the patient
- Biokinetics of radiopharmaceuticals (uptake, retention, excretion)
- Distance to the patient
- Length of time spent near the patient

Different radionuclides have different modes of decay and will emit different types of radiation (alpha, beta and/or gamma). The type and energy of the emitted radiation will result in different range and penetration ability. The exposure will be in direct proportion to the amount of activity administered to the patient, while the excretion rate affects the time radiation protection measures need to be in place.
Exposure will typically arise from external radiation directly from the patient or from the excreta, including vomit, diapers etc. Therefore, the most important radiation protection measure is to keep distance to the patient and to minimize the time spent near the patient and the patient excreta.

ISO 18310-2 (4) describes a method to determine the contribution to effective dose from external exposure to the caregiver in the vicinity of a patient treated with I-131. It is based on the read-out from a personal dosemeter worn by the caregiver.

Internal exposure

Depending on the pathways of excretion for the radiopharmaceutical (e.g. through saliva, urine, faeces, exhalation, regurgitation, sweat, breastmilk), there may be a potential risk of contamination and intake of radioactive material. In particular this should be considered if the patient is incontinent.

A more detailed description of contamination pathways and radiation protection guidelines for selected radionuclide therapies can be found in EC-RP194 (5).

Criteria for release of patients

Dose constraints could be established either by national legislation, by the regulatory body or by the licensee, depending on the national legislation. Combining dose limits, dose constraints and relevant exposure scenarios, one can derive nuclide specific activity limits and dose rates to establish the release criteria. In cases where internal exposure is of relevance, nuclide specific activity limits should be derived on the basis of particular exposure scenarios of relevance for the therapy in question.

A simple measurement of dose rate at a given distance from the patient rarely provides enough information to decide whether the patient can be released or not. Often assessment of more parameters is needed. For

instance, dose rate measurements only relays information on external exposure, and therefore only applies to scenarios where external exposure is the dominant exposure pathway.

In case of fractionated treatments where the radiopharmaceuticals are administered in repeated cycles, e.g. in Ra-223 treatments, the repetition of the treatment should be taken into account when setting dose constraints for carers and comforters. The total dose from repeated cycles should also be considered if the patient is working in close proximity to colleagues who, as members of the public, are subject to different dose constraints.

Establishing relevant exposure scenarios

For a specific treatment, the applied radiopharmaceutical and the administered activity should be taken into account when identifying relevant exposure scenarios, following the steps below:

- Consider *who* is likely to be exposed
- Consider under *which circumstances* the exposure takes place
- Calculate (or evaluate) *the dose* that the exposure results in
- Conclude on the basis of the dose calculation/evaluation to which extent instructions on behavior are needed.

Who is likely to be exposed?

When releasing a patient especially the exposure of carers and comforters and members of the public are relevant. Family members, who live in the same household as the patient or participate in helping and nursing the patient, may be considered carers and comforters. Whether family members under 18 years may in some cases be considered carers and comforters or are always considered members of the public depends on national legislation.

Under which circumstances does the exposure take place?

International guidelines such as the EANM therapy guidelines (6) and Summary of Product Characteristics for the radiopharmaceutical can be consulted in order to decide which exposure situations are relevant.

Patient interview

When identifying who might be exposed and the circumstances pertaining to this exposure, the specific living situation for each individual patient should be evaluated. This will reveal the potential exposure situations for which doses need to be calculated or evaluated. For this purpose, a questionnaire may be constructed, including questions about the patient's daily habits. See Appendix A for an example.

The considerations necessary for a hospital before release of patients are also described in chapter 4 in EC RP97 (3).

Process for deciding the necessary instructions on behavior

Figure 1 illustrates a process for determining relevant exposure situations to consider and for deciding whether instructions on behavior are needed. The listed types of exposed persons and exposure situations in the figure is not exhaustive and should only be considered as examples.

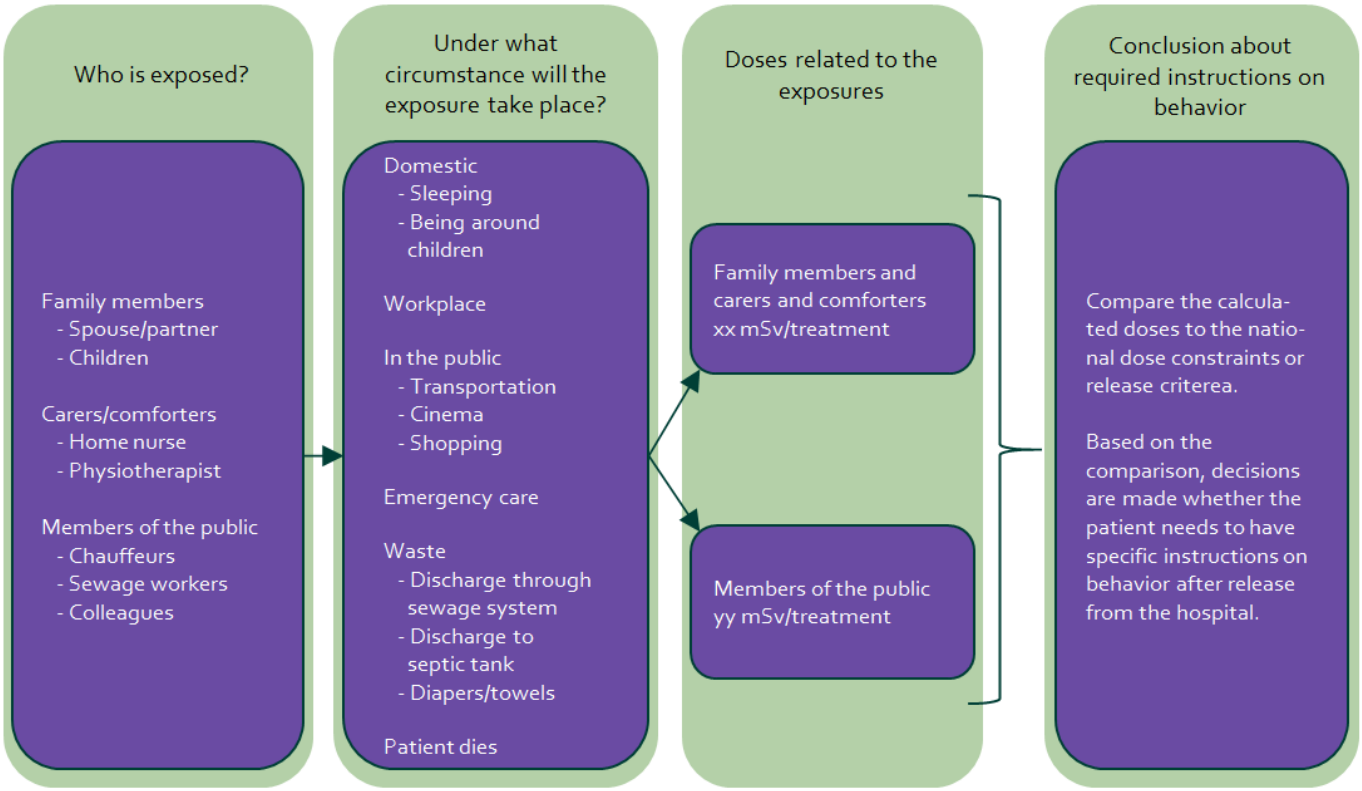

***Figure 1**: Process steps for deciding necessary instructions on behavior*

Instructions on behavior

Instructions on behavior should be supplied in writing to the patient and the caregiver (carers and comforters). The patient should only be released from hospital if the patient is deemed able to follow the instructions given.

Examples of typical instructions on behavior (as applicable) are listed below.

- Isolation at home for a given number of days.
- Limitation of public presence (shopping, theaters, public transportation).
- Reduction of exposure to family members (especially children) by keeping distance and reducing time.
- Avoidance of contact of family members, carers, comforters and other persons present with eating and drinking utensils and with bed linen (especially pillow coverings) from the patient.
- Personal hygiene, frequency of doing laundry, cleaning of surfaces, vacuum cleaning, ventilation of areas, changing of bed linen.
- Preferably a separate toilet for the patient; used sitting down and flushed several times after each use.
- Cleaning of spilt urine or other body fluids with paper which is disposed through the toilet.
- Leave from work for a given number of days, contingent on working situation and taking into account if work includes adult or child/infant contact.
- Discontinuation of breastfeeding for a number of weeks before treatment. This is recommended for most radiopharmaceuticals in order to reduce the radiation dose to the breast tissue and the risk of milk leakage that may contaminate clothing etc. with radioactive substances.
- Avoidance of pregnancy for a defined period based on dose calculation to potential fetus (7).

- Management of waste (diapers, sanitary towels).
- Use of sanitary facilities with no flushing to sewage system, e.g. dry toilets in summer residence/holiday homes.

Considerations regarding instructions on behavior are also described in chapter 5 in EC RP97 (3).

Management of radioactive waste in the patient's home

The generation of radioactive waste in the patient's home should be minimized. The anticipated amount and activity of radioactive waste produced in the home needs to be considered when deciding on whether or not to release the patient. Radioactive waste management needs to be considered separately taking into account municipal waste management systems, including both household waste and sewage.

In the Nordic countries, there are differences in the national legislations regarding restrictions to radioactive waste management in a patient's home. The hospital should, based on an appropriate safety assessment, describe the safe management of radioactive waste in the patient's home. If the derived instructions cannot be followed, the patient should stay at the hospital.

There are different clearance levels in the Nordic countries, and also EU-BSS (1) and IAEA-BSS (8) have recommendations for clearance values. If clearance values are used, the hospital should also take into consideration that some radiopharmaceuticals may contain impurities of long-lived radionuclides, e.g. Lu-177 with long lived impurities of Lu-177m (half-life 161 days), and Ra-223 with long lived impurities of Ac-277 (half-life 21,8 years).

The responsibility for considering radioactive waste management lies with the licensee. However, the regulatory authorities may establish local requirements or exemptions, e.g. the regulatory body may consider exemption of a particular waste fraction from a sub-group of patients based on nation-wide evaluation.

ICRP publication 94 (9) states that radionuclides discharged from radionuclide therapy into modern sewage systems result in doses that are well below the limits for the sewer workers and the public. A series of screening calculations performed by SSM (10) confirms this statement.

An example of how to calculate the activity concentrations in diapers is described in (11), section 2.3.

IAEA has published generic models for use in assessing the impact of discharges of radioactive substances to the environment (12). A revision of the generic models is in preparation.

Patient Card

Upon release from the hospital, the patient could be supplied with a card or bracelet stating that the patient is undergoing radionuclide therapy and provide instructions for emergency situations, e.g. situations requiring medical care. HERCA developed a template for such a card in 2011 (13).

The instructions on the patient card for emergency situations should state, that lifesaving treatments should always be prioritized, and can be performed safely by first responders and other emergency and medical staff. A patient card might also prove useful where the patient triggers an alarm, e.g. in the security scan in an airport. Instructions on how to handle questions, e.g. direct phone number to relevant hospital department may be added.

Graded Approach

A method to quantify the degree of necessary precautions and living rules is to use the graded approach method, where the living rules are decided on a patient specific basis based on a set of evaluation parameters, e.g. the patient questionnaire mentioned earlier.

Table 2 illustrates the principle of graded approach with respect to release of patients

Patient evaluation parameters	Level of severity after individual evaluation of the patient	Based on individual assessment consider following action	Typical instructions on behavior
Radionuclide, calculation of doses, patient health such as incontinency, mental state, other behavioral issues, family situation (children, pregnancy)		Stay at hospital	Hospital rules
		Can be released, but with major restrictions on behavior	Isolation at home
		Can be released with a set of restrictions on behavior	Limitations on the use of public transportation and social activity
		Can be released with minor restrictions on behavior	Avoid contact to infants
		Can be released without restrictions	Normal living

***Table 2**. Example of the use of graded approach*

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- NCRP Report no. 155, Management of Radionuclide Therapy Patients (2008).

Appendix A

Example of questionnaire for patients

Personal

1. Is there a possibility that you are pregnant?
2. Are you breastfeeding?
3. Do you have difficulties holding your urine or faeces?
4. Do you suffer from constipation?
5. Are you menstruating?
6. Are you under other medical treatments, e.g. dialysis?

Home conditions

7. Do you live with adults?
8. Do you live with children?
9. Do you live with someone who is dependent on your help?
10. Are you dependent on regular help from other people?
11. Do you share a bed with another person?

Working conditions

12. What is your profession?
13. Do you work with children?
14. How do you get to work?
15. Is your travel time to work longer than two hours?
16. How many hours a day are you near your nearest colleague?
17. What is the distance to your nearest colleague?

Planned vacation / travel / entertainment

18. Are you planning longer trips or holidays in the near future?
19. Are you planning any entertainment activities in the near future? For example, Cinema, theatre or parties.

Children and pregnant women

20. Can you avoid prolonged close contact with children or pregnant women in the next weeks?

Travelling arrangements from hospital

21. How will you get home from the hospital?
22. Is your travel time home from the hospital longer than one hour?


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