

## SUMMARY OF SUBMISSIONS AND RESPONSES ON PATIENT DISCHARGE RECOMMENDATIONS

	COMMENT	RESPONSE
001	<ol style="list-style-type: none"> <li>Generally I found the document to be acceptable. In particular the activity release limits are fairly reasonable, although - as I have commented many times in the evolution of this document - there is no real reason to have any activity release limit on pure beta emitters.</li> <li>In "Sectn 3. Instructions for Patients", the recommendations specify providing *individual* advice which should take into account the patient's travel, domestic and work arrangements and even their preferred recreational activities. I would submit that this is much too large an impost on the staff of a busy therapy practice. It seems to me that it would be entirely adequate to have generic instructions, which can be varied in the few cases where the patient has unusual circumstances. Each patient will naturally be asked about their circumstances during discussions about their treatment.</li> </ol>	<ol style="list-style-type: none"> <li>Comment noted.</li> <li>The <i>Recommendations</i> now state that individualised instructions relevant to the patient's medical and social circumstances should be provided. The working group noted that there may be a legal obligation to tailor advice to individual patients.</li> </ol>
002	<ol style="list-style-type: none"> <li>The use of I-125 for prostate treatment has raised concerns on what to do on the death of the patient - autopsy and cremation. If it were appropriate it would be good to get some official guidance in this or some other document.</li> </ol>	<ol style="list-style-type: none"> <li>The RHS 18, <i>Code of practice for the safe handling of corpses containing radioactive materials</i> (1986), is expected to be revised in the near future.</li> </ol>
003	<ol style="list-style-type: none"> <li>I was pleased to see that instructions regarding social activities, specifically shopping and the cinema have been included as well as travel by public transport. It is stated that this should not exceed 2 hours. Such a guideline is extremely useful, and instructing a patient to "minimise as far as practicable" is not always very meaningful.</li> <li>Moreover I would like to see this extended to include a guide for contact with babies and young adults;</li> <li>Does this include children over 12 years old (or over 80kg)</li> <li>Are there stages of pregnancy which are more dangerous than others. (Traditionally the first trimester is the worst, but recent data suggests that in fact the last trimester can be the most sensitive time)</li> <li>Are pets at risk at any stage post discharge. we usually recommend that the pet does not sleep on the bed with the patient for the next three days, but we have no data to suggest that this is in fact necessary.</li> <li>At what stage post therapy is it safe for the patient to attempt to become pregnant.</li> <li>Some departments enforce a "no kissing" period of up to three days. Is there any suggestion that this is required?</li> <li>I particularly liked the recommendation to carry an identity card.</li> </ol>	<ol style="list-style-type: none"> <li>Comment noted.</li> <li>The working group considered such additional guidance as too specific for these <i>Recommendations</i>. It is suggested that the ANZSNM, ARPS or other appropriate body may wish to prepare guidelines for specific radionuclides, e.g. I-131 or Y-90 microspheres, to be available on their Web sites.</li> <li>Restrictions on children have been included in the <i>Recommendations</i>.</li> <li>This question is not relevant to these <i>Recommendations</i>.</li> <li>This question is not relevant to these <i>Recommendations</i>.</li> <li>This question is too specific for these <i>Recommendations</i>. The working group noted that such advice was more appropriate to a code of practice for nuclear medicine.</li> <li>Too specific.</li> <li>Comment noted.</li> </ol>
004	<ol style="list-style-type: none"> <li>The current document, although far from perfect, is a big improvement on previous drafts. My main comments at this stage (given that I doubt that any major changes can be made) are as follows:</li> <li>I still think the document could be extended without too much trouble to incorporate the discharge of patients who have received diagnostic amounts of radiopharmaceuticals. It might even amount to a few simple changes and a change of title to "Recommendations for the discharge of patients to whom radioactive substances have been administered"</li> <li>Although the document is quite good from a regulatory point of view in that it lays out what is required in a very general way, it is quite evident that application of the recommendations in this document in a practical setting</li> </ol>	<ol style="list-style-type: none"> <li>Comment noted.</li> <li>The working group was of the view that diagnostic radiopharmaceuticals were more appropriate to a different type of document, such as a code of practice for nuclear medicine.</li> <li>The working group suggested that this information may be made available on the ANZSNM Web site.</li> </ol>

	<p>will require some prescriptive advice. This prescriptive information could perhaps be incorporated in a companion document (perhaps in electronic form, with a facility for rapid updating as required). The United States Nuclear Regulatory Commission (NRC) and the NRL in New Zealand, for example, have already taken this approach for quite a few of their most recent regulatory guidelines.</p>	
<b>005</b>	<ol style="list-style-type: none"> <li>1. In general, the ARPANSA document is well written and it provides clear guidelines on the management of patients who are discharged after undergoing treatment with radioactive substances. The discussion on methods of assessing radiation dose at time of discharge is helpful.</li> <li>2. The College does not propose any modification to the draft and would be pleased to endorse the document in its current form.</li> </ol>	<ol style="list-style-type: none"> <li>1. Comment noted.</li> <li>2. Comment noted.</li> </ol>
<b>006</b>	<ol style="list-style-type: none"> <li>1. I am a nuclear physician, who is actively involved in therapeutic Nuclear Medicine. In general, I am in agreement with the proposed recommendations, particularly with respect to the increase in limits for Yttrium-90. However, I would like to draw your attention to an area that should be considered.</li> <li>2. Iodine-131 Lipiodol therapy involves the administration of approximately 2,000 MBq of this compound directly in the hepatic artery, with uptake by the primary liver tumour. There is very little excretion of this activity and hence achieving the discharge level of 600 MBq is largely dependent on natural decay. This may take up to 10–14 days. Patients find it very difficult to remain in isolation for this period of time (psychologically distressing) and it is also very trying for the attendant nursing staff. For several of our patients we have been granted an exemption by the local Radiation Protection Branch to allow early discharge of these patients provided that they: <ol style="list-style-type: none"> <li>a) will be going to a suitable home environment</li> <li>b) are fully independent/medically well</li> <li>c) their “spouse” or primary carer is provided with a radiation monitor personal digital dosimeter and phones in their readings to our Radiation Safety Officer on a daily basis – to be reviewed after the first few cases.</li> <li>d) The patient is reviewed and measured in our Department every few days (depending on distances to be travelled) to determine when Discharge levels are reached.</li> <li>e) The Radiation Branch is fully informed</li> </ol> This has worked very well and given that there are a number of other treatments eg Iodine-131 labelled antibodies where in-hospital isolation times will be much longer than usually seen, this situation will arise more frequently in the future.</li> <li>3. If ARPANSA does not wish to make a specific recommendation on this issue, it could consider inserting a paragraph regarding patients facing prolonged in-hospital isolation and the potential for suitable patients to be released early with approval and supervision of the local regulatory bodies.</li> </ol>	<ol style="list-style-type: none"> <li>1. Comment noted.</li> <li>2. Section 2.2 of the <i>Recommendations</i> has been re-written to allow for the discharge of patients when an estimate of effective doses to other persons can be shown to comply with the dose limits and constraints.</li> <li>3. As for 2 above.</li> </ol>
<b>007</b>	<ol style="list-style-type: none"> <li>1. Essentially, it has found the document to be acceptable. However, a number of its members who have considerable experience in the treatment and management of patients with radioactive substances, and expertise in the associated radiation safety issues have provided a number of comments and suggestions. A summary of these follows.</li> </ol>	<ol style="list-style-type: none"> <li>1. Comment noted.</li> </ol>

<p><b>2. Iodine 125 discharge limit</b>  The limit imposed for I-125 is unacceptable for the use of I-125 in an eye plaque where activities are up to 3 GBq are not uncommon. The “no limit” situation previously existing has the advantage that it accommodates new treatments not envisaged at this time. If an arbitrary limit is placed on discharge based on present practice it may result in the restriction of a new treatment until the recommendations can be revised. If a limit is felt necessary it should be based on the 25 <math>\mu</math>Sv per hour at 1 metre. According to the ARPANSA report, that would allow about 200 GBq of I-125 and 1 TBq of Pd-103. Certainly the present limit on I-125 needs to be substantially increased.</p> <p><b>3. Iodine 131 discharge limit</b>  Most expressions of concern relate to the recommendations for the discharge of patients with I-131, the unsealed radioactive isotope mainly used in hospitals. The document uses both a 600 MBq body burden (Annex 2) and a 25 <math>\mu</math>Sv/hour at 1 metre in air dose rate (Section 2.2) as possible limits. It implies that 600 MBq equates to 25 <math>\mu</math>Sv/hour at 1 metre. This is not supported by a number of our members although it is agreed that the dose rate limit is in reality more lenient than the activity one. The main concern, however, is that a 600 MBq activity limit for I-131 may be far too stringent in terms of:</p> <ol style="list-style-type: none"> <li>a) the potential radiation exposure to carers,</li> <li>b) the additional radiation burden that hospitalisation would place on sensitive young members of our nursing staff</li> <li>c) and the financial cost of admitting patients for prolonged periods.</li> </ol> <p>This recommendation seems to have ignored the economic and social aspects of the ALARA concept. Also, it does not appear to take account of measured clearance rates, clinical condition of patient, domestic situation of patient at home, age of carer, professional advice of institutional physicist or RSO to calculate and document carer dosimetry. This is surprising given that Section 2.1 suggests that a reasonable dose constraint to aim for is &lt; 5 mSv to carers, a figure that the ACPSEM endorses, although it is recommended that in such cases carers should have given informed consent.</p> <p>4. Whilst it is acknowledged that the document needs to be kept as simple as possible, it is not accepted that the gold standard for estimating potential public exposure is the residual body burden. This fails to take into account any body self-shielding, individual clearance rates, effective half-life of the radioisotope, clinical condition, domestic circumstances of the patient etc. All of these will have a substantial impact on the potential exposure values of a carer and other members of the patient’s family. It is believed that the approach adopted by the FDA and the IEPM in the UK, which allows institutions to estimate potential effective doses to the carer, based on individual patient data, is an eminently suitable alternative and one which should be allowed. By all means retain the activity limit as an over-riding limit for those institutions that may be unable or unwilling to undertake such calculations.</p> <p><b>5. Gold 198 discharge limit</b>  The limit for Au-198 should be the same as that of I-131 since they deliver the same dose for a given activity. In fact the shorter half-life of Au-198 would argue that it</p>	<p>2. Note 3 for Annex 1 now states that no activity limit is necessary for shielded I-125 or Pd-103 plaques/applicators.</p> <p>3. This point has been addressed in the revised <i>Recommendations</i>. The title of Annex 2 has been modified from “... may be discharged from hospital” to “... may be administered to outpatients”.</p> <p>4. Section 2.2 of the <i>Recommendations</i> has been re-written to allow for the discharge of patients when an estimate of effective doses to other persons can be shown to comply with the dose limits and constraints.</p> <p>5. Gold-198 is a sealed form, approximates to a point source and is not excreted. 400 MBq approximates 25 Sv/hour at 1 metre.</p>
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	<p>could have a higher discharge activity rather than lower since the integrated dose will be less for continuing contact with the patient.</p> <p><b>6. Radiation Terminology</b> The document is technically in error in parts, in that it uses imprecise dosimetry language. For example, Section 2.1 refers to radiation dose to the public whereas this should be effective dose and in Section 2.2 it measures dose-rate in <math>\mu\text{Sv/hr}</math> when it should be absorbed dose rate to air in <math>\mu\text{Gy/hr}</math>. This refers to a physical measurement, not a biological one. Given that the target audience is presumably physicists and nuclear medicine personnel, it is felt that the dose terms should be used correctly. However, it is acknowledged that many radiation monitors do display dose-rates in <math>\mu\text{Sv/hr}</math> which, whilst not technically correct, is becoming the normal practice.</p> <p><b>7. Patient instructions</b> In “Section 3. Instructions for Patients”, the recommendations specify providing ‘individual’ advice which should take into account the patient’s travel, domestic and work arrangements and even his/her preferred recreational activities. This may be much too large an impost on the staff of a busy therapy practice. It may be entirely adequate to have generic instructions, which can be varied in the few cases where the patient has unusual circumstances. Each patient will naturally be asked about their circumstances during discussions about their treatment.</p> <p><b>8. Travel</b> The document recommends the following “It is recommended that the time of travel by public transport for the patient returning home should not exceed two hours” however this time should be dependent on the activity. It is therefore recommended that this is modified to “It is recommended that the time of travel by public transport for the patient returning home should not exceed two hours when patients are discharged with the maximum activity tabulated in Annex 2.”</p> <p><b>9. Special Circumstances</b> To further allow the introduction of new methods of treatment not envisaged in this document and to make allowance for the special circumstances discussed above under “Iodine-131 discharge limit”, the dose limits in Annex 1 and 2 should allow higher activities where it can be demonstrated to an appropriate regulatory authority that dose rates at a metre are less than <math>25 \mu\text{Sv/hour}</math>, doses to the public will be kept below <math>1 \text{ mSv}</math> and the risk of contamination and/or loss of radioactive sources is negligible.</p> <p>10. Finally, whilst the document is specifically for Australian use, our membership base includes New Zealand (and elsewhere) and since many other Professional Bodies and Standards Documents embrace both Australia and New Zealand, it is felt that care should be taken to ensure that there is consistency in law and practice between states of Australia and with New Zealand.</p>	<p>6. The radiation dosimetry nomenclature has been revised. Specific items are treated in the responses to comments from 008.</p> <p>7. The “Instructions for Patients” now states that individualised instructions relevant to the patient’s medical and social circumstances should be provided to each patient.</p> <p>8. Section 2.9 “Use of Public Transport by the Patient” has been amended to state “The time of travel by public transport for the patient returning home should not exceed two hours when the patient is discharged at a maximum dose rate of <math>25 \text{ Sv/hour}</math> at 1 metre, or the maximum activity given in Annex 2”.</p> <p>9. Section 2.2 of the <i>Recommendations</i> has been re-written to allow for the discharge of patients when an estimate of effective doses to other persons can be shown to comply with the dose constraints.</p> <p>10. A representative of the NRL (New Zealand) is an invited observer on the Radiation Health Committee.</p>
008	<ol style="list-style-type: none"> <li>1. Very useful guidance document.</li> <li>2. Repetition and overlap of material, particularly in Section 2 and Annex 3.</li> <li>3. Debate about the connection between the primary criteria (effective dose less than <math>1 \text{ mSv/year}</math> for members of the public and <math>5 \text{ mSv/event}</math> for carers), the maximum activity</li> </ol>	<ol style="list-style-type: none"> <li>1. Comment noted.</li> <li>2. Cannot be avoided if Annex 3 is to be “stand alone”.</li> <li>3. Based on empirical studies of iodine-131 therapies.</li> </ol>

<p>limits and the measurement of radiation intensity (as an equivalent dose rate in <math>\mu\text{Sv/h}</math> at various distances from the patient).</p> <ol style="list-style-type: none"> <li>4. Should it be explained that the activity limits are recommendations only and that patients may be discharged, or treated as outpatients, with greater activities if an estimation of the ED to members of the public and carers by an experienced medical physicist demonstrates that the primary criteria would probably be satisfied? Ie. should the recommended activity limits be taken as default values if the institution does not wish to do patient-specific estimates. Would the approval of the regulatory body be necessary if an institution chose to exceed the recommended activity limits or dose rate at discharge on the basis of its own ED estimates, other than for novel therapies?</li> <li>5. Would a companion set of generic Instructions for Patients, eg. for I131 patients, be useful for institutions without medical physics support? could there be more references in the Bibliography, eg. the ANZAPNM guide for Sr89, and anything for Rhenium188 or Sm153?</li> <li>6. Difficult to follow the order of forms and radionuclides in Section 2, Annex 1, Annex 2 and Annex 3. Section 2 considers dose rates - sealed forms – unsealed forms - max activities, so Annex 1 and Annex 2 are in the right order. Annex 3 should also be dose rates – sealed forms – unsealed forms. Strict alphabetical order of radionuclides not necessary in Annex 3, eg. grouping of Cs137 and Ir192 together is helpful. Similarly, for unsealed forms it would be helpful if the pure beta emitters (P32, Sr89 and Y90) were grouped together at the end of Annex 3, with the remaining unsealed form beta/gamma nuclides taken in alphabetical order.</li> <li>7. p2. para 3 line 8: delete “It is recognised that...”</li> <li>8. lines 10-14: replace last two sentences with “The external dose rate from iodine-131 distributed within a patient may be approximated by an ‘inverse 1.5 power’ relationship from 1 to 3 metres. Thus, 25 <math>\mu\text{Sv/h}</math> at 1 metre may be taken as equivalent to 9 <math>\mu\text{Sv/h}</math> at 2 metres and 5 <math>\mu\text{Sv/h}</math> at 3 metres.” Delete the reference in the footnote.</li> <li>9. p2 para 4 replace 1<sup>st</sup> sentence with “The total external radiation dose to members of the public and family members will depend not only on the dose rate at the time of discharge but also on the physical decay rate of the radionuclide, the biological clearance rate of the radioactive substance from the patient and the time spent by the patient in proximity to these persons.”</li> <li>10. line 7: replace “... effective half-lives may differ from that of iodine-131.” with “... rates of physical decay and biological clearance may differ from those of iodine-131.”</li> <li>11. line 8: replace “... the effective half-life...” with “... the rates of physical decay and biological clearance ...”</li> <li>12. p3 para 1 line 3: at end, add “(See Section 3.3, Instructions for Patients.)”</li> <li>13. p3 para 3 Delete paragraph. Why are iodine-131 patients singled out? Are the recommendations in the preceding paragraph not sufficient?</li> <li>14. P4 para 4 line 8: after “hospital” insert “or treated as an outpatient”</li> <li>15. p4 para 3 line 3: after “in advance of” insert “or at the time of”</li> <li>16. line 6: delete “, the radiation characteristics of the radionuclide.”</li> <li>17. p5 para 2 line 4: after “... good personal hygiene ...” insert</li> </ol>	<ol style="list-style-type: none"> <li>4. Section 2.2 of the <i>Recommendations</i> has been re-written to allow for the discharge of patients when an estimate of effective doses to other persons can be shown to comply with the dose limits and constraints.</li> <li>5. Outside the scope of these <i>Recommendations</i>. The appropriate professional bodies may wish to provide guidance via their Web sites, or by other means.</li> <li>6. Agreed. The sequence of Annex 3 has been rearranged as indicated.</li> <li>7. Agreed. Amended to “The patient does not ....”.</li> <li>8. Agreed and amended as proposed.</li> <li>9. Agreed and amended as proposed.</li> <li>10. Agreed. Replaced by “... the rates of physical decay and biological clearance may differ.”</li> <li>11. Agreed and amended as proposed.</li> <li>12. Agreed. “(See Section 3, Instructions for Patients)” added.</li> <li>13. Recommendations concerning public transport have been transferred to a new Section 2.9 “Use of Public Transport by the Patient”, which does not refer to iodine-131. Section 2.5 now contains the amended instruction “After oral administration of an unsealed radionuclide (e.g. iodine-131 for thyroid therapy), the patient should remain at the hospital or clinic until such time as the patient is unlikely to vomit the administered dose.”</li> <li>14. Agreed and amended.</li> </ol>
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<p>“... including separate cleaning or storage of any clothing or personal articles which may be contaminated, ...”</p> <p>18. p5 at end Insert sentence “The Bibliography lists publications which contain guidance on precautions for several specific radionuclide therapies.”</p> <p>19. p8 Annex 1 table caption: replace with “Recommended maximum activities of radionuclides in sealed form at which a patient may be discharged from hospital or which may be administered to an outpatient, such that the effective dose limit to any member of the public is unlikely to be exceeded.”</p> <p>20. Table: after column 1 insert column of physical half lives, to assist in the interpretation of Note 2 to the table. In Note 2, replace “spent in close proximity to” by “of prolonged physical contact with”</p> <p>21. p9 Annex 2 table caption: replace with “Recommended maximum activities of radionuclides in unsealed form at which a patient may be discharged from hospital or which may be administered to an outpatient, such that the effective dose limit to any member of the public is unlikely to be exceeded.”</p> <p>22. Table: after column 1 insert column of physical half lives, for interest in unfamiliar radionuclides and consistency with Annex 1.</p> <p>23. Note 4, 1<sup>st</sup> sentence: delete “... not taken up by the target organ or otherwise immobilised”</p> <p>24. Note 4, last sentence: after “... 24 hours” insert “after discharge from the hospital or clinic.”</p> <p>25. P10 Annex 3 Caption should be “Rationale for the recommended maximum activities administered to outpatients and the maximum dose rates and activities for discharge of inpatients from hospital”</p> <p>26. Delete 1<sup>st</sup> and 2<sup>nd</sup> paragraphs, already covered in Section 2.1 and 2.2.</p> <p>27. P10 para 3 1<sup>st</sup> sentence: delete “level”; after “recommended” insert “maximum dose rate”; move “derived” in front of “primarily”.</p> <p>28. Line 3: Insert new sentence after “... thyroid disorders.” “Experience has shown that the dose limits and constraints for exposure to members of the public, family and carers are unlikely to be exceeded if patients are treated with up to 600 MBq of iodine-131 as outpatients or if patients are discharged from hospital when the external dose rate is less than 25 µSv/h at one metre, provided that the patient observes some simple restrictions on close contact with other persons.”</p> <p>29. point a: after “the activity” insert “and distribution”</p> <p>30. Point c: replace with “the physical decay rate and the biological clearance rate of the radioactive substance in the body (often represented by the effective half-life derived from the physical half-life and an assumed monoexponential biological clearance rate);”</p> <p>31. Point d: after “shielding” insert “provided”</p> <p>32. Swap points c. and d. so that the three factors which contribute to the external dose rate are grouped first and the two factors which contribute to the integral dose are grouped second.</p> <p>33. P11 para 1 line 3: after “... effective half-life” insert “of the radioactive substance”</p> <p>34. P11 para 2 delete. Already covered in Section 2.2</p> <p>35. P11 para 3 line 6: replace “given the shielding” with “because of the inherent shielding provided”</p> <p>36. P11 para 4 Clarify the requirements in the US Regulatory Guide 8.39: “... allows for patients to be treated with a</p>	<p>15. Agreed and amended.</p> <p>16. Amended to “... the relevant radiation characteristics ...”.</p> <p>17. The working group considered this to be too detailed and suggested the proposed instruction should be put into a separate guideline.</p> <p>18. Agreed and amended as proposed.</p> <p>19. The table caption of Annex 1 has been amended to “Maximum activities of radionuclides in sealed forms at the time of discharge”. The term “discharge” has been defined in an additional paragraph in Section 2.1 to mean “... the return of the patient to the community...”.</p> <p>20. A column of the physical half-lives of the radionuclides has been added to the table of Annex 1. The “spent in close proximity to” in Note 2 has been retained.</p> <p>21. The title of Annex 2 has been amended to “Maximum activities of radionuclides in unsealed forms which may be administered to outpatients”.</p> <p>22. The physical half-lives of all the radionuclides in Annex 2 are now given in an additional new column in the table.</p> <p>23. Agreed and deleted.</p> <p>24. Agreed and addition made.</p> <p>25. Agreed and the title of Annex 3 amended to “Rationale for the Recommended Maximum Activities Administered to Outpatients and the Maximum Dose Rates for Discharge of Inpatients from Hospital”.</p> <p>26. These paragraphs have been retained in order to keep Annex 3 as “stand alone”.</p> <p>27. Amended to read “The recommended maximum equivalent dose rate ...”. “Derived” has been moved in front of “primarily”.</p> <p>28. Agreed and amended as proposed.</p> <p>29. Agreed and amended as proposed.</p> <p>30. Amended to read “the physical decay rate and biological clearance of the radioactive substance in the patients body”. The material in parentheses has not been included as it was considered by the WP to be unnecessary.</p> <p>31. Agreed and amended.</p> <p>32. Agreed and points swapped.</p> <p>33. Agreed and amended.</p> <p>34. Has been retained in order for Annex 3 to be “stand alone”.</p> <p>35. Has been amended to “... the shielding provided by the patient’s body ...”</p> <p>36. Amended to “... allows a default patient</p>
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	<p>radionuclide as an outpatient provided that a constraint of 5 mSv effective dose to a member of the public is achievable. This can be assessed by patient-specific calculations based on the radiopharmaceutical residence time in the body and the likely patterns of close contact, or – for iodine-131 - by the default values of 33 mCi (1220 MBq) or an external dose rate less than 70 µSv/h at one metre.”</p> <p>37. P11 para 5 1<sup>st</sup> sentence: insert “Consequently,” at beginning, insert “located” after “radionuclides”, and move the sentence to end of this paragraph.</p> <p>38. P11 para 6 line 1: Full stop after “ excreted activity.” Replace “and the provisos” with “The activity restrictions”</p> <p>39. line 2: replace “stated in the footnotes.” With “listed in the Notes in Annex 2.”</p> <p>40. line 7: delete “external”</p> <p>41. P12 para 1 line 1: replace “mostly concentrated in the abdominal organs” with “(which is mostly concentrated in the abdominal organs)”</p> <p>42. P12 para 3 line 1: replace “exposure rates” with “dose rates”</p> <p>43. P12 para 4 line 1: replace “exposure rate” with “dose rate”</p> <p>44. line 3: insert comma after “emission”; replace “the possibility of external contamination” with “potential contamination from excreted activity”</p> <p>45. What is the point of the last sentence?</p> <p>46. P12 para 5 line 1: replace “exposure rate” with “dose rate”</p> <p>47. P12 para 6 line 4: terminate the sentence after “lost”; delete “and are to” and substitute “Consequently these sources must”.</p> <p>48. P12 para 7 line 2: replace “exposure rate” with “dose rate”</p> <p>49. P12 para 8 line 1: replace “of” with “contained in”</p> <p>50. P13 para 1 line 1: insert comma after “administered”</p> <p>51. P13 para 3 line 4: replace “a footnote” with “the Notes listed in Annex 1”</p>	<p>release at ....”. Patient specific discharge is now treated in the new Section 2.2.</p> <p>37. The sentence has been amended to “External dose rate limits are not applicable to these radionuclides when they remain within the patient’s body”, but has been retained as the first sentence.</p> <p>38. Agreed and amended.</p> <p>39. Agreed and amended.</p> <p>40. Agreed an amended.</p> <p>41. Replaced by “... when mostly concentrated in the abdominal organs”.</p> <p>42. Agreed and replaced by “... equivalent dose rates ...”.</p> <p>43. Agreed and replaced by “... equivalent dose rate ...”.</p> <p>44. Agreed and amended.</p> <p>45. The sentence has been retained.</p> <p>46. Agreed and replaced by “... equivalent dose rate ...”.</p> <p>47. Sentence terminated after “lost”. Substituted by “These sources must ...”.</p> <p>48. Agreed and replaced by “The equivalent dose rate ...”.</p> <p>49. Agreed and amended.</p> <p>50. The sentence has been amended to “Studies have shown that, for the commonly activity range of these radionuclides, ...”.</p> <p>51. Agreed and amended.</p>
<p><b>009</b></p>	<p>I fully agree that the sentence you highlighted in section 1.3 is important and would be acceptable to all in sundry. The problem is that in reading the document one is confronted with the requirements outlined in Clauses 2.2 &amp; 2.5 with the latter referring to activity limits in Annex 2. My reading, and I know I was not alone in my interpretation, is that we would have to meet both the dose rate and activity limits before satisfying the discharge criteria. If that is not intended and we can discharge at our discretion as per clause 1.3 then this needs to be stated more emphatically. If clause 2.2 and 2.3 are intended only for those who don’t consider each patient on their merits then perhaps that needs to be stated.</p>	<p>The Draft has been extensively amended to clarify the conditions for discharge from hospital and the treatment of outpatients. “Discharge” has been defined and a new Section 2.2 allows for patient discharge based on individual patient circumstances and estimates of effective doses to other persons.</p>
<p><b>010</b></p>	<p>Supports the rationale for the modification, particularly with regard to conforming to the 1 mSv/yr dose limit for members of the general public. We agree that measurement of maximum dose rate at 3m is a more practical means of assessing risk than the prescribed activity.</p> <p>We suggest the following modification to the document:</p> <p>(a) Section 1.3 “Scope”, paragraph ii, be replaced with the following: “The requirements for discharge of individual patients should be assessed by a physician <b>or radiologist</b> holding an appropriate radiation licence, <b>who may consult with a medical physicist with experience in radiation safety. The licensee retains</b></p>	<p>Comment noted.</p> <p>(a) “Physician” has been replaced by “medical specialist”.</p>

	<p><b>the right to vary advice after consideration of the patient’s medical and social circumstances.</b></p> <p>(b) Section 3 “Instructions for patients”, paragraph iv, commencing “The discharged patient...” should be deleted. Patients receive written or verbal advice from the nuclear medicine physician as part of their medical consultation and this usually contains a contact telephone number. Further, patients often have follow-up visits with their own referring specialist. Council believes that the proposed “discharge card” is superfluous and may reinforce negative emotions regarding the perceived adverse effects of medical radiation.</p>	<p>(b) The paragraph “The discharged patient ...” has been amended to “On the day of treatment, a written record of the treatment should be provided to the referring doctor and, where appropriate, to the patient and/or carers. This record should include the following information:”.</p> <p>The working group’s view that a “card” is useful has been supported by a number of the comments received. The instruction concerning the “card” has now been placed after the dot points detailing the information to be provided to the referring doctor, patient and/or carers as “The patient should also be provided with a card containing the above information. The card should be carried by the patient at all times until the date specified”.</p>
<p><b>011</b></p>	<ol style="list-style-type: none"> <li>1. Should the “1978” in the third line of Annex 4, ARPANSA RPS Publications, be italicised for consistency with the title <i>Environment Protection Act (Nuclear Codes) Act</i>?</li> <li>2. The ARPANSA publications in Annex 4 need updating.</li> <li>3. The title of the Patient Discharge Recommendations in Annex 4 (4th publication) should be “Recommendations <b>for</b>” not “on” to be consistent with the Foreword and the title of RPS 1.</li> <li>4. Does a table of “Radiation Protection Authorities” need to be included as an Annex of the document?</li> <li>5. The publisher and date of publication (e.g. Pergamon Press, Oxford and AGPS, Canberra) are missing from the references in the Bibliography, usually at the end of the reference but before any page numbers.</li> </ol>	<ol style="list-style-type: none"> <li>1. To be amended to follow agreed style.</li> <li>2. To be updated.</li> <li>3. Amended to “for”.</li> <li>4. To be included.</li> <li>5. To be amended to a consistent style.</li> </ol>
<p><b>012</b></p>	<ol style="list-style-type: none"> <li>1. The precautions to be taken depend on the individual circumstances of the patient (eg are they able to look after themselves, are there young children at home, will they be in close contact with anyone who is pregnant, etc etc). The time for which these precautions will need to be taken depends on the dose constraint set, the external exposure rate from the patient, how much activity was administered, and the rate at which activity is cleared from the patient. General calculations can be made for various circumstances, but there is a great deal of variability from patient to patient. The problem, therefore, is far from straightforward, and the draft ARPANSA document gives no prescriptive information as to how to go about it.</li> </ol>	<ol style="list-style-type: none"> <li>1. Section 2.2 of the <i>Recommendations</i> has been re-written to allow for the discharge of patients when an estimate of effective doses to other persons can be shown to comply with the dose limits and constraints.</li> </ol>
<p><b>013</b></p>	<p>You requested measured dose rates at a distance of 1 m from patients containing Re<sup>188</sup>. We measured the dose rate using SmartION 2120S Ion Chamber dosimeter. As you may know, the maximum energy of photons of Re<sup>188</sup> is about 2 MeV. It should be noted that this might be in the range where Bragg-Grays assumptions of electron equilibrium for normal ion chamber thicknesses start to break. The manufacturer’s supplied energy response is measured up to 1.4 MeV (±15%) and for 6 MeV photons (±15%). Nevertheless the fraction of total photon energy emitted by Re<sup>188</sup> photons with energies higher than 1.4 MeV is approximately 6%. This may increase in the radiation fields around patients but we still believe that we have obtained measurements with sufficient accuracy.</p> <p>Model 2120S measures in sieverts (Sv) the following quantities:</p> <ul style="list-style-type: none"> <li>- Superficial dose equivalent H'(0.07),</li> <li>- Ambient dose equivalent H*(10).</li> </ul>	<p>Measurements of external dose rates from a Re-188 source at the centre of a 10 cm cylindrical phantom by R Fox of Royal Perth Hospital and R. Smart’s estimation of the dose rate from Re-188 in a patient liver (by a comparison with Tc-99m) gave a dose rate of 6.0 uSv/h at 1 metre from a 1,000 MBq distributed source. The maximum activity for an outpatient has been amended to 4,000 MBq, and a private communication from R. Fox cited.</p>

	<p>The measurements were as follows:  <b>N=6 <math>\mu</math>Sv/h at 1 meter per GBq of Re<sup>188</sup></b></p> <table border="1"> <thead> <tr> <th>Quantity</th> <th>Average</th> <th>Range</th> </tr> </thead> <tbody> <tr> <td><b>H'(0.07)</b></td> <td><b>7.4</b></td> <td><b>5.5 – 9.0</b></td> </tr> <tr> <td><b>H*(10)</b></td> <td><b>6.7</b></td> <td><b>5.3 – 8.4</b></td> </tr> </tbody> </table> <p>We do not feel that using one limiting measured dose rate at a distance of 1 m can serve as a gauge of radiation protection measures for all radionuclides and radiopharmaceuticals used in therapy. Dose rate of 25 uSv/h at 1 meter is frequently exceeded in diagnostic nuclear medicine. Furthermore measured dose rate at 1 meter around a patient will be highly variable. Worse still absorbed doses will be even more uneven. Non-symmetrical uptake of radionuclides may make radiation absorbed dose fields around patients vary by a factor of 10.</p>	Quantity	Average	Range	<b>H'(0.07)</b>	<b>7.4</b>	<b>5.5 – 9.0</b>	<b>H*(10)</b>	<b>6.7</b>	<b>5.3 – 8.4</b>	
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<p><b>014</b></p>	<ol style="list-style-type: none"> <li>1. “We have now on at least 2 occasions that I know about, had people who have had suspected fractures, come back into the workplace while the Tc99 “loads up” into the bone. Usually the suggestion has been go back to work for a couple of hours. There seems to be nothing in the recommendations about these situations.</li> <li>2. I know the source is much smaller, not as penetrating etc, but when these people return to a workplace where other workers wear dose badges, they can affect the badge.</li> <li>3. Since these are recommendations for discharge only, this temporary release of patients back to the workplace may not truly constitute a discharge.”</li> </ol>	<ol style="list-style-type: none"> <li>1. The <i>Recommendations</i> do not address diagnostic radiopharmaceuticals. These situations are considered to be more appropriate for a code of practice for nuclear medicine.</li> <li>2. Not relevant to these <i>Recommendations</i>.</li> <li>3. “Discharge” has now been defined in Section 1.2 as the any return of the patient into the community.</li> </ol>									
<p><b>015</b></p>	<ol style="list-style-type: none"> <li>1. The title of 2.6 refers to Outpatients, but the word “outpatient” does not appear in the text of this section. We say that “the patient should be retained in hospital following the administration if the activity of the radionuclide administered exceeds the amount given in Annex 1 for sealed sources or Annex 2 for unsealed sources of the radionuclide in question.” To me this <i>implies</i> that the patient can be treated as an outpatient if the activity does not exceed these activities, BUT we don’t specifically say so. Perhaps the above section should be replaced with “the patient may be treated as an outpatient if the activity of the radionuclide administered does not exceed the amount given in Annex 1 for sealed sources or Annex 2 for unsealed sources of the radionuclide in question.”</li> <li>2. The second sentence of 2.6 is superfluous as it repeats what is in section 2.3</li> <li>3. Section 3 “Instructions for Patients” includes a written record for the referring doctor. Why is this in a section on instructions for the patient?</li> <li>4. The title of Annex 1 needs “of the patient” to be added at the end.</li> <li>5. Annex 3 repeats a lot of material from the text of the Recommendations. This was done originally because Annex 3 was to be a stand-alone document for the public submission phase, and not included in the Recommendations themselves. It would provide the basis on which the limits were set, and would be useful as/when the Recommendations were revised again in the future. If Annex 3 is to be included in the Recommendations, we could omit the first 2 paragraphs as these repeat what is in 2.1 and 2.3 without giving the “rationale”. The rationale for the dose rate limit begins at paragraph 3.</li> </ol>	<ol style="list-style-type: none"> <li>1. Agreed with modification. The first paragraph of Section 2.6 to be replaced by “In general, the patient may be treated as an outpatient if the activity of the radionuclide to be administered does not exceed the activity given in Annex 1 for sealed sources or Annex 2 for unsealed sources.”</li> <li>2. Agreed. Sentence to be deleted.</li> <li>3. To be retained.</li> <li>4. Agreed with modification. The title of Annex 1 to be amended to “Maximum activities of radionuclides in sealed forms at which a patient may be discharged”. The use of “which” and “may” makes the title of Annex 1 consistent in style with the title of Annex 2.</li> <li>5. The working group did not express a strong preference, however the Radiation Health Committee requested that the first two paragraphs of Annex 3 be retained.</li> </ol>									

	<p>6. “Equivalent dose rate” and “dose rate” are intermingled eg. For Indium-111 dose rate rather than <b>equivalent</b> dose rate is used. I am not actually sure why ‘equivalent’ is used some times and not others. There are several instances of dose rate rather than equivalent dose rate in this section.</p> <p>7. On page 15 Par 1 the word effective halflife is used. This (for reasons I am unclear about) has not been used in the main document - replaced by physical and biological clearance?</p> <p>8. On page 15 (Rationale) Par 2 re transport. As you have added in 2.9, I think it should say .....<b><i>“should not exceed two hours when the patient is discharged at a maximum dose rate of 25uSv/hr at 1 metre or at the maximum activity”</i></b> Many times an inpatient may be discharged at a lot less than 25 uSv/hr when this limit could be adjusted.</p>	<p>6. Agreed. Radiation Health Committee determined that ambient dose equivalent rate will be used consistently where applicable.</p> <p>7. Agreed to replace “effective half-life” by “the physical decay rate and the biological clearance rate”.</p> <p>8. Agreed. The latest Draft has already been amended to “The time of travel by public transport for the patient returning home should not exceed two hours when the patient is discharged at a maximum dose rate of 25 uSv/hour at 1 metre, or at the maximum activity given in Annex 1”. The sentence will be further amended to “ambient dose equivalent rate” and “Annex 1 or Annex 2”.</p>
<b>016</b>	No major problem noted. A few of the ACPSEM members were concerned that the 600 MBq limit for iodine-131 was too restrictive.	The 600 MBq limit for iodine-131 has general acceptance by other interested parties.
<b>017</b>	<p>Queried use of “equivalent dose rate”.</p> <p>Queried the application of 2.3 versus 2.6, ie it may be confusing as to whether dose rate takes precedence over activity level.</p>	<p>The working group considered the use of “equivalent dose rate” as appropriate and desirable.</p> <p>Section 2.6 will now state “In general, the patient may be treated as an outpatient if the activity of the radionuclide to be administered does not exceed the activity given in Annex 1 for sealed sources or Annex 2 for unsealed sources.” This will remove the uncertainty in the case of outpatients.</p>
<b>018</b>	<p>Currently in Annex 3 we say under the iodine-131 heading that:</p> <p>“A residual patient activity of 600 MBq of iodine-131 results in an approximate dose rate of 25 uSv/hour at 1 metre taking into account the shielding provided by the patient’s body.”</p> <p>There seems to be considerable debate on the dose rate at 1 m from a patient containing 600 MBq, both in the literature and within the working party. Measurements indicate that the 25 uSv/hour at 1 metre is often exceeded for 600 MBq, and I think that this needs to be reflected in some form in Annex 3. As the 25 uSv/hour value applicable to all gamma emitters seems to have general acceptance, this should be retained.</p>	<p>Sentence should be amended to:</p> <p>“A residual patient activity of 600 MBq of iodine-131 results in an equivalent dose rate in the range 25 - 40 uSv/h at 1 metre, taking into account the shielding provided by the patient’s body. The more restrictive criterion of 25 uSv/h at 1 metre is included in these <i>Recommendations</i>”.</p>

**NOTE: Comments 015 – 018 were on a later draft that had been revised in light of the earlier comment.**