



**DOCUMENTS  
OF THE NRPB**

**Stable Iodine Prophylaxis**

**Recommendations of the 2nd UK Working Group  
on Stable Iodine Prophylaxis**

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**National Radiological Protection Board  
Chilton, Didcot, Oxon OX11 0RQ**



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# **STABLE IODINE PROPHYLAXIS**

## **Recommendations of the 2nd UK Working Group on Stable Iodine Prophylaxis**

CHAIR: PROFESSOR M C SHEPPARD

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This report from the Working Group reflects understanding and evaluation of the current scientific evidence as presented and referenced in this document.



## Executive Summary

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### TERMS OF REFERENCE

- 1 In 1989 a UK Working Group on Stable Iodine Prophylaxis was convened by the Department of Health (DH) to provide advice on all aspects of the use of stable iodine as a protective measure following an accidental release of radioiodine. The recommendations of this Group were published in 1991 (UK Working Group, 1991). In developing its advice, the Group reviewed guidance published by the World Health Organisation (WHO, 1989). In late 1999, WHO updated its guidance in the light of additional information gained from the incidence of thyroid cancer in children following the accident at the Chernobyl nuclear power plant in April 1986 (WHO, 1999). The National Radiological Protection Board (NRPB), at the request of DH, convened a 2nd UK Working Group to review the latest WHO guidance in the context of emergency planning for nuclear accidents in the UK. This Working Group was also asked to review the Patient Information Leaflet currently supplied with stable iodine tablets in the UK, as questions had been raised whether it was written in a style appropriate to its target audience.
  - 2 The terms of reference of the 2nd UK Working Group on Stable Iodine Prophylaxis were:
    - (a) to consider whether, in the light of both the new WHO guidance and the experience gained after the Chernobyl reactor accident, revisions are required to the advice published by the 1st Working Group in 1991,
    - (b) to consider whether the NRPB Emergency Reference Levels (ERLs) for stable iodine prophylaxis require amendment,
    - (c) to look at the leaflet that accompanies the stable iodine tablets and, if appropriate, suggest revisions to the text.
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### ACTIVITIES OF THE 2ND WORKING GROUP

- 3 The Working Group met three times during 2000, and completed its report by correspondence in 2001. The membership of the Working Group is given on page 7.
  - 4 The Working Group reviewed the revised WHO guidance and the information published since 1991 on the risks of thyroid cancer in children from radioiodine and the risks of side effects from stable iodine. In particular, it reviewed data compiled on the incidence of thyroid cancers in children following the accident at the Chernobyl nuclear power plant in 1986. It considered whether the NRPB ERLs were still appropriate, in the light of the new data. It also reviewed a range of other recommendations given by the 1st Working Group, concerning the chemical form of stable iodine tablets and practical issues concerning implementation of stable iodine prophylaxis. Finally, it reviewed the Patient Information Leaflet that is required, by law, to be included in each box of tablets and provided suggestions for information to be included in a separate information leaflet to be handed out to the public when stable iodine tablets are distributed.
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**SUMMARY OF MAIN RECOMMENDATIONS AND CONCLUSIONS**

5 The Working Group's main concern is to highlight the potential vulnerability of young children following an accidental release of radioiodine. Inhaled and ingested radioiodine is preferentially taken up by the thyroid and, compared with adolescents and adults, young children's thyroids are more radiosensitive. Also, such children are likely to consume greater quantities of milk, a food which can become contaminated within a few days of an atmospheric release of radioiodine. The Working Group's main recommendation is therefore that the prime focus of emergency planning against releases of radioiodine should be the protection of newborn babies (neonates), children under ten years, and pregnant and nursing women. Stable iodine prophylaxis has the potential to provide total protection from intakes of radioisotopes of iodine. Generally, the Working Group expects stable iodine prophylaxis to be planned for protection against inhaled radioiodine only. Protection against ingestion of radioiodine in foods is better achieved using food restrictions, and UK emergency plans envisage this. However, the Working Group advises that if, in unforeseen circumstances, the planned food restrictions cannot be implemented promptly, then stable iodine prophylaxis should be used as a temporary measure to provide protection for young children against the ingestion exposure pathway, until the food restrictions can be imposed.

6 The Working Group's wider recommendations are summarised below.

**ERLs for stable iodine prophylaxis**

7 With respect to the ERLs for stable iodine prophylaxis, the Working Group makes the following recommendations for consideration by NRPB.

- (a) The priority for emergency planning for stable iodine prophylaxis should be the protection of neonates, children aged under ten years, and pregnant and nursing women.
- (b) Detailed emergency plans should provide for the stable iodine tablets to be administered promptly, as the health benefit afforded reduces with increased delay in administration.
- (c) It is not necessary to move to a system of age-related ERLs in the UK, provided that the lower ERL adopted is appropriate for children aged under ten years and neonates, and that the relevant planning emphasises the priority in administration to be afforded to these age groups.
- (d) The combination of sheltering (or evacuation) with stable iodine prophylaxis within UK emergency planning forms an important element in the provision of overall protection and, therefore, the existing link between the ERLs for sheltering and stable iodine prophylaxis should be retained.
- (e) Following a reactor accident, the ingestion of contaminated milk is potentially the greatest thyroid exposure pathway: provided appropriate food restrictions are put in place promptly to protect children against this exposure pathway, then it is appropriate for the ERLs for stable iodine prophylaxis to be compared with expected doses from inhalation only; otherwise it is the sum of the expected doses from inhalation and ingestion that should be compared with the ERLs.
- (f) Consideration should be given to reducing the upper ERL for stable iodine prophylaxis to 100 mGy averted thyroid dose from inhalation: this would retain flexibility for planning and response for the administration of stable iodine to adults,

but signals the fact that stable iodine prophylaxis has now been demonstrated to have minimal side effects.

- (g) The administration of stable iodine tablets to children aged under ten years and neonates should generally be planned at the level of the lower ERL. The Working Group considers that the upper ERL is too high for adequate protection of these age groups.
- (h) The lifetime risk to a child, exposed to 30mGy thyroid dose (the currently recommended lower ERL), of developing thyroid cancer is in the range 1: 1000 to 1: 10 000.
- (i) A reduction of the lower ERL to the WHO recommended value of 10mGy would undoubtedly provide additional protection to children who would currently not receive prophylaxis. However, in determining whether to reduce the lower ERL, this benefit would need to be weighed against the detrimental consequences of changing existing emergency plans – for example, a possible delay in protection for those most at risk resulting from administration of stable iodine tablets to a larger population.
- (j) NRPB should continue to review the risk estimates given here for internal exposure of the thyroid to radioiodine, in the light of future data on the incidence of thyroid cancer in those exposed in Belarus, neighbouring parts of Russia and northern Ukraine.
- (k) The provision of appropriate information and support for those not receiving stable iodine prophylaxis should be considered as part of emergency planning.

The Working Group invites NRPB to review its advice on ERLs for stable iodine prophylaxis on the basis of these points, as elaborated in the main text of its report.

#### **Iodine tablets**

- 8 The Working Group recommends that the age-related dosages of iodine and the tablet sizes recommended by the 1st Working Group are still appropriate for use in the UK. These are set out in the table below.

Age group	Equivalent mass of iodine (mg)	Potassium iodate (mg)	Potassium iodide (mg)*
Adults	100	168.9	130
Children aged 3 – 12 years	50	84.4	65
Children aged 1 month – under 3 years	25	42.2	30–35
Neonates (birth – under 1 month)	12.5	21.1	15

*Recommended dosages for potassium iodate and potassium iodide*

\*These values, taken from WHO (1989), are rounded.

In addition, the Working Group advises the following.

- (a) There are no medical grounds for preferring the iodate form over the iodide form.
- (b) The pre-distribution of stable iodine tablets can be helpful in specific circumstances, but widespread pre-distribution to individual households is not advised.
- (c) DH should review the future provision of adequate tablet stocks.

## *Stable Iodine Prophylaxis*

- (d) All hospitals with maternity units, either in a detailed emergency planning zone around a nuclear site or serving the area of these zones, should stock iodine crystals for the preparation of accurate dosages of stable iodine for neonates in the first few days of life.
- (e) There are no medical grounds for restricting the sale of stable iodine tablets to the public; however, emergency plans should not rely upon voluntary purchase.

### **Information provision**

9 The Working Group makes the following recommendations.

- (a) The Patient Information Leaflet should be revised to specify that one quarter tablet be given to neonates,
  - (b) A separate, more 'user-friendly' leaflet should be prepared for distribution to the public at the time of an accident,
  - (c) The appropriate authorities should give consideration to the planned provision of relevant advice to other groups needing information on stable iodine after an accident, in particular to GPs.
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### **REFERENCES**

- UK Working Group (1991). Nuclear accident countermeasures: iodine prophylaxis. London, Department of Health, Health and Social Subjects Report 39.
- WHO (1989). Guidelines for iodine prophylaxis following nuclear accidents. Copenhagen, WHO Regional Office for Europe, Environment Health Series No. 35.
- WHO (1999). Guidelines for iodine prophylaxis following nuclear accidents: update 1999. Geneva, WHO/SDE/PHE/99.6.
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*Stable Iodine Prophylaxis*

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## INTRODUCTION

### Background

- 1 In 1989 a UK Working Group on Stable Iodine Prophylaxis was convened by the Department of Health (DH) to provide advice on all aspects of the use of stable iodine as a protective measure following an accidental release of radioiodine. The recommendations of this Group were published in 1991 (UK Working Group, 1991). In developing its advice, the Group reviewed guidance published by the World Health Organisation (WHO, 1989). In late 1999, WHO updated its guidance in the light of additional information gained from the incidence of thyroid cancer in children following the accident at the Chernobyl nuclear power plant in April 1986 (WHO, 1999). The National Radiological Protection Board (NRPB), at the request of DH, convened a 2nd UK Working Group to review the latest WHO guidance in the context of emergency planning for nuclear accidents in the UK. This Working Group was also asked to review the Patient Information Leaflet currently supplied with stable iodine tablets in the UK, as questions had been raised whether it was written in a style appropriate to its target audience.
- 2 The terms of reference of the 2nd UK Working Group on Stable Iodine Prophylaxis were:
  - (a) to consider whether, in the light of both the new WHO guidance and the experience gained after the Chernobyl reactor accident, revisions are required to the advice published by the 1st Working Group in 1991,
  - (b) to consider whether the NRPB Emergency Reference Levels (ERLs) for stable iodine prophylaxis require amendment,
  - (c) to look at the leaflet that accompanies the stable iodine tablets and, if appropriate, suggest revisions to the text.

### National Radiological Protection Board

- 3 In the UK, NRPB has the statutory responsibility for specifying emergency reference levels (ERLs) of radiation dose for the implementation of stable iodine prophylaxis. Its current advice (NRPB, 1990) was published shortly before the report of the 1st UK Working Group on Stable Iodine Prophylaxis, but takes full account of the recommendations made by that Group. NRPB is therefore invited to consider the observations and recommendations developed in this 2nd Working Group report, and to review its advice on ERLs for stable iodine prophylaxis accordingly.
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## CURRENT UK ADVICE ON STABLE IODINE PROPHYLAXIS

- 4 In the UK, the intervention levels (ILs) adopted for stable iodine prophylaxis are those recommended by NRPB in 1990 (NRPB, 1990), and endorsed by the 1st Working Group in 1991 (UK Working Group, 1991)\*. These ILs are expressed in terms of doses to children, as children are generally more vulnerable to radiation than adults. NRPB advises that a balance needs to be struck between the expected benefits of carrying out

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\* The intervention level for stable iodine prophylaxis is the level of radiation dose above which a single (age-related) dosage of stable iodine should be administered.

a countermeasure and any likely harmful consequences. In the context of stable iodine prophylaxis, the principal expected benefit is a reduction in the risk of thyroid cancer incidence, whilst the main harmful consequences are potentially the risk of adverse reactions to stable iodine and the cost of maintaining plans to enable prompt administration of stable iodine, should the need arise. The expected reduction in risk of thyroid cancer incidence is directly related to the IL. Both the risk of side effects and the cost of maintaining plans are linked to the number of people to whom it is planned to provide stable iodine, which is in turn linked to the IL. NRPB recommends pairs of ILS (upper and lower ERLs), and those currently recommended for stable iodine prophylaxis are equivalent to 30 and 300 mGy averted thyroid dose to a child\*. NRPB advises that the lower (30 mGy) ERL should generally be adopted in emergency planning, but in circumstances where implementing the countermeasure would be particularly difficult or harmful, then values up to the upper ERL (300 mGy) could be used<sup>†</sup>.

5 The ERLs for stable iodine prophylaxis were recommended on the basis of balancing the risks of exposure to radioiodine and the expected consequences of the countermeasure, as they were understood in 1990. This understanding is summarised below.

- (a) The lifetime risk of thyroid cancer incidence in a child exposed to external radiation, at the exposure levels and rates likely after an accident, was around  $5 \times 10^{-3} \text{ Gy}^{-1}$ .
- (b) The lifetime risk of thyroid cancer, from internal irradiation of the thyroid of a child, might be as much as equal to that from external irradiation, at the exposure levels and rates likely after an accident, ie  $5 \times 10^{-3} \text{ Gy}^{-1}$ .
- (c) Approximately 10% of total thyroid cancer incidence would be fatal.
- (d) The risk to adults from exposure to radioiodine was small.
- (e) The risks from taking stable iodine were not great enough to influence significantly the decision on the values chosen for the ERLs.
- (f) The practical problems and costs associated with maintaining and implementing plans for the distribution of stable iodine were similar to those associated with planning for and implementing the countermeasure of sheltering.

6 Based on this understanding, it was concluded that if the risk of fatal thyroid cancer alone were considered, the lower ERL for administering stable iodine should be set in the range 30–100 mGy thyroid dose to a child. However, it was recognised that there was significant uncertainty surrounding the risk estimate for children (see Appendix A). In order both to be cautious and to link the countermeasure with that of sheltering (see paragraph 7), the lower ERL was actually set at the lower end of the range, ie 30 mGy thyroid dose.

7 NRPB further recommended that stable iodine prophylaxis should not normally be used as a stand-alone countermeasure. This is because stable iodine prophylaxis only

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\* The NRPB ERLs are actually expressed as 30 and 300 mSv. For the purposes of this document 'mGy' and 'mSv' can be assumed to be the same (since radioisotopes of iodine emit low LET radiation).

† Strictly, the lower ERL is recommended for use in circumstances where 'the disadvantages of implementing the countermeasure are judged to be small (eg where few people would be involved, and the implementation of the countermeasure has been planned in detail in advance)' and the upper ERL is recommended for use in circumstances where 'the disadvantages of implementing the countermeasure are judged to be large (eg where many people would be involved, or where the implementation of the countermeasure has not been planned in advance)' (NRPB, 1990).

has the potential to protect against one exposure pathway and one group of radionuclides (ie intakes of radioisotopes of iodine), whilst exposure following a radiological accident is likely to encompass other pathways (eg external exposure) and other radionuclides. For this reason, NRPB linked the ERLs for stable iodine prophylaxis with those for sheltering\*. Currently, off-site UK emergency planning always provides for stable iodine tablets to be administered in conjunction with advice either to shelter or to evacuate.

- 8 Both NRPB and the 1st Working Group recommended that stable iodine prophylaxis should be planned as a countermeasure only against inhalation of radioiodine. This is because it is UK policy and practice to plan for food restrictions to protect against the ingestion pathway. Whilst repeated (daily) dosages of stable iodine would protect the thyroid gland from prolonged exposure to radioiodine in foods, the continued administration of stable iodine to provide protection against exposures that can be avoided by other means is clearly not desirable (and for neonates would be harmful). Given the infrastructure of Western Europe, it is extremely unlikely that an accident could affect UK food supplies to an extent that contaminated foods could not be replaced promptly by uncontaminated foods.
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#### POST-CHERNOBYL THYROID CANCER INCIDENCE

- 9 Following the accident at the Chernobyl nuclear power plant in 1986 a significant rise in thyroid cancer cases in the exposed children has been observed in Belarus, a small part of the Russian Federation and the northern part of the Ukraine. Childhood thyroid cancer is normally rare, and there can be little doubt that the increase, which is most marked in the youngest exposed children, is due to exposure to the radioisotopes of iodine present in the fallout (Williams, 1996). About 1800 thyroid cancer cases have occurred up to 1998 in those who were children or adolescents at the time of the accident (UNSCEAR 2000). The rate of incidence of thyroid cancer in children aged 0–1 year at exposure is approximately twice that of those aged 2–3 years at exposure, and approximately 16 times that of those aged 8–9 years at the time of the accident (Cardis, 1999). There are suggestions that the annual rate of incidence has peaked or is beginning to decline, but this is complicated by the changing morphology and molecular biology of the tumours (Santoro *et al*, 2000; Williams *et al*, 2000). The data for adult incidence are less clear cut: there has been a three- to four-fold increase recorded in thyroid cancer in adults in Belarus, but a three-fold increase seen in parts of the Russian Federation has been attributed to screening (Ivanov *et al*, 1999). An increase in thyroid cancer in those exposed as adults cannot be excluded on present evidence, but it is at most relatively small. Further study is needed because of the possibility that tumours with a longer latent period may yet occur.
- 10 Several papers have been published providing indicative estimates for the observed risk per unit dose from internal exposure to radioiodine, by children, following the accident at Chernobyl (Astakhova *et al*, 1998; Jacob *et al*, 1998, 1999, 2000; Heidenrich

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\* Sheltering is the countermeasure of remaining inside solidly constructed, reasonably airtight buildings with doors and windows closed and ventilation systems turned off. The restriction of airflow into the building during the passage of a radioactive plume reduces inhalation exposure, and the solid construction of the walls reduces external exposure from radioactive material outside the building.

*et al*, 1999). None of these papers is definitive; some of them are based on geographical correlations, while the uncontrolled nature of the exposures means that detailed case-control studies with accurate dose estimates are difficult to achieve. Moreover, the short half-life of the dominant radionuclide, iodine-131, means that it is unlikely that the uncertainties surrounding the dose estimates will be refined in the future. On the basis of these studies it is clear that the risk per unit dose for children aged under ten years is higher than that for adults (eg Heidenrich *et al* (1999) suggest a factor of three between children aged under ten years at exposure and older children). The much higher relative risk of incidence in young children compared with adults was probably in part due to the dietary dependence of the children on local contaminated milk supplies.

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#### REVISED WHO GUIDANCE

- 11 The full text of the revised WHO guidance is published (WHO, 1999). In summary, taking account of information from studies on external exposure to radioiodine published within the last ten years, and also information now available as a result of the Chernobyl accident, WHO offers the following guidance.
- (a) The lifetime risk of thyroid cancer from external irradiation of children is around  $10^{-2} \text{ Gy}^{-1}$ .
  - (b) The lifetime risk of thyroid cancer, from internal irradiation of the thyroid of a child, may be as much as equal to that from external irradiation.
  - (c) The risk to adults exposed at ages under 40 years is small.
  - (d) The risk to those aged over 40 years when exposed is negligible.
  - (e) The risk of adverse reactions to a single dose of stable iodine is very small in all age groups (less than one in one million).
- 12 In 1996, WHO became a joint signatory, with other international agencies, to the 'Basic Safety Standards' recommendations of the International Atomic Energy Agency (IAEA, 1996). The Basic Safety Standards include a recommendation for a single IL for stable iodine prophylaxis of 100 mGy averted thyroid dose. However, based on improved evidence of both the very low risk of adverse reactions to stable iodine in all age groups, and the increasing risk from radioiodine with decreasing age at exposure, the recent WHO guidance is that three, age-related, ILs be adopted as follows:
- (a) 10 mGy averted thyroid dose for children up to 18 years, and for pregnant and lactating mothers (ie a factor of three lower than the NRPB lower ERL),
  - (b) 100 mGy averted thyroid dose for adults aged under 40 years old (ie a factor of three to four higher than the NRPB lower ERL),
  - (c) 5 Gy projected thyroid dose for adults aged over 40 years (the level of dose above which deterministic injuries are expected to occur).
- 13 WHO further advises that, unless effective protection from ingestion of foods contaminated with radioiodine (particularly milk for infants) can be achieved by appropriate food countermeasures, the ILs given above should apply to the sum of doses from both inhalation and ingestion. Where stable iodine is administered to provide protection against inhalation only, then a single dose of stable iodine is

sufficient. Where food countermeasures cannot be reliably implemented, it may be necessary to provide daily doses of stable iodine over a period of days or even weeks to children.

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#### **RISK ESTIMATES FOR THYROID EXPOSURE TO RADIOIODINE**

14 The 2nd Working Group has reviewed the data on the risks of thyroid exposure to radioiodine. A summary of how risk estimates have been refined over the ten years since NRPB published its advice in 1990 is provided in Appendix A. Based on this information, the Working Group has drawn the following conclusions.

- (a) The lifetime risk of thyroid cancer incidence, from external exposure of children aged under ten years, is around  $13 \times 10^{-3} \text{ Gy}^{-1}$ .
- (b) The lifetime risk of thyroid cancer incidence, from internal exposure to radioiodine of children aged under ten years, may be as much as equal to that for external exposure, ie around  $13 \times 10^{-3} \text{ Gy}^{-1}$ .
- (c) The uncertainty on these thyroid cancer risk estimates for childhood exposure is around a factor of two to five.
- (d) The stochastic risk to adults is small, and negligible for those exposed at over 40 years of age. However, if the rate of thyroid cancer incidence attributable to the Chernobyl accident continues to increase, then it may be necessary to review the conclusions relating to adults in a few years' time.
- (e) The Working Group's conclusions on risk estimates are consistent with the revised WHO guidance.

15 These conclusions mean that the risk estimates for internal exposure of children to radioiodine at low doses and low dose rates, on which the NRPB ERLs for stable iodine prophylaxis are based, may have been underestimated by a factor of two to three. This variation is within both past and present estimates of uncertainty surrounding the risk estimate.

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#### **RISKS FROM STABLE IODINE**

16 The Working Group has also reviewed the information now available on the risks associated with the administration of stable iodine, in the context of the UK. The details of this review are given in Appendix B. In summary, following the Chernobyl accident, widespread administration of stable iodine (in the form of potassium iodide) took place in Poland, but no serious side effects were seen. In addition, advances in the preparation and storage of potassium iodide formulations in other countries have demonstrated this form to be as stable as potassium iodate. The Working Group has therefore drawn the following conclusions.

- (a) The risks of adverse effects from the administration of a single dose of stable iodine (at the age-related dosages recommended by the Working Group) are extremely low and should not be considered a significant cause for concern when determining ILs for stable iodine prophylaxis.

- (b) This conclusion is consistent with the revised WHO advice.
  - (c) There is no strong medical reason for preferring the use of potassium iodate over potassium iodide, or vice versa.
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#### **SHOULD CHANGES BE MADE TO THE NRPB ERLs?**

- 17 The Working Group has concluded that the stochastic risk estimates recommended by the revised WHO guidance for thyroid cancer incidence following internal exposure to radioiodine in children are supported by recent studies. It has also concluded, again in accordance with the revised WHO guidance, that the very low risk of adverse effects from the administration of a single dose of stable iodine has been adequately demonstrated. However, agreement on these two issues is not a sufficient basis for also recommending the UK adopts the WHO guidance concerning intervention criteria. Whilst risk estimates must form an important input to decisions on appropriate ILs, other factors are also relevant, as discussed below.

#### **ILs for different age groups**

- 18 The Working Group considers it essential that the highest priority for stable iodine prophylaxis should be the protection of the thyroids of young children. It strongly recommends that emergency planning within the UK explicitly incorporates this emphasis.

- 19 The Working Group recognises that one way of achieving this is to recommend lower ILs for young children than for other age groups, as WHO has done. However, the Working Group also recognises practical difficulties in implementing an emergency response based on age-related ILs, including:

- (a) greater complexity of the response, potentially leading to delays in the administration of stable iodine tablets and, hence, a lowering of the protection afforded,
- (b) difficulties in explaining to the public why certain age groups should not take stable iodine tablets, with, again, the risk of delaying the administration.

- 20 The Working Group suggests that it is not necessary to move to a system of age-related ILs in the UK, provided that the IL adopted gives adequate protection for young children and that planning emphasises the priority to be afforded to young children. This priority and emphasis can be achieved by appropriate advice to emergency planners and emergency response organisations and by the information given on the leaflet accompanying the tablets. Since the risk of adverse effects from taking stable iodine is extremely low for all age groups, little harm is incurred if stable iodine tablets are administered to all age groups on the basis of an IL that is appropriate for young children.

#### **Link with sheltering**

- 21 The countermeasure of sheltering involves individuals going inside solidly constructed and reasonably airtight buildings, closing doors and windows, and turning off ventilation systems. The building materials can provide shielding against external irradiation, and can slow down the rate of ingress of radioactive material that could be inhaled. The Working Group considered the doses and risks that might be averted during a nuclear emergency, both following implementation of either stable iodine

prophylaxis or sheltering, and following implementation of stable iodine prophylaxis and sheltering in combination. On the basis of this investigation, the Working Group reached the following conclusions.

- (a) In developing an overall response strategy, it is important to consider the risks arising from all exposure pathways and radionuclides, and to all organs (ie not just the thyroid). This is important, even for a release consisting only of iodine-131: whilst stable iodine prophylaxis has the potential to reduce a significant part of the risk resulting from inhalation of iodine-131, it provides no protection against external irradiation by this radionuclide (ie from the plume or from contamination on the ground).
- (b) Sheltering, as a stand-alone countermeasure, does not provide a substantial degree of protection against thyroid cancer risk, when radioisotopes of iodine are major components of the release.
- (c) Used together, stable iodine prophylaxis and sheltering offer a greater proportional degree of protection than simple multiplication of their individual effectiveness would indicate. This is because they offer substantial protection against different dose pathways: stable iodine prophylaxis against exposure to inhaled radioiodine, and sheltering against external irradiation.

- 22 The Working Group therefore considers that the combination of sheltering (or evacuation) with stable iodine prophylaxis forms an important element in the provision of overall protection. It recommends that the existing link between the ERLs for sheltering and stable iodine prophylaxis be retained.

#### **Link with food restrictions**

- 23 It is clear that the main exposure pathway to radioiodine from the Chernobyl accident, in Belarus, the Russian Federation and the Ukraine, was the ingestion of contaminated food, particularly milk. The Working Group recognises that the UK food infrastructure is very different from that in the former Soviet Union, and that plans are in place for the prompt implementation of food restrictions based on criteria agreed between the member states of the European Union (EC, 1987, 1989, 1990). However, the Working Group wishes to emphasise the importance of ensuring such plans are effective. This Working Group therefore endorses the advice of the 1st Working Group, that stable iodine prophylaxis should be planned for protecting against the inhalation exposure pathway only, provided other prompt measures are planned to protect young children from exposure to radioiodine in foods. In the event of unforeseen circumstances preventing prompt implementation of food restrictions, then the Working Group recommends that stable iodine be administered on a daily basis to those children at risk, until such time as adequate food restrictions can be implemented. In this case, the IL adopted for administering stable iodine should be compared with the sum of the thyroid doses from inhalation and ingestion, as opposed to the inhalation thyroid dose alone. Owing to the sensitivity of the neonate (newborn baby) and fetus thyroid to large doses of iodine, repeated administration of stable iodine should be avoided for neonates and pregnant and lactating women; in the event of a delay in imposing appropriate food restrictions, clear advice on dietary consumption is essential for these groups.

**Reduction of the upper ERL for stable iodine prophylaxis**

24 The Working Group recognises the need for some flexibility both in planning for, and in response to, an actual accident. This is required both in practical terms and in recognition of the large difference in the risks of exposure between adults and children. The Working Group is, therefore, in favour of retaining an upper, as well as a lower, ERL. However, if the existing upper ERL of 300 mGy were applied to children aged under ten years, the resultant risk of thyroid cancer incidence to those most exposed might approach 1 in 250. Abolishing the upper ERL would mean losing the desired flexibility of response for other age groups. In addition to the need for retaining flexibility, the Working Group recommends that both the uncertainty on the stochastic risk estimate for children (a factor of two to five) and any practical implications should be taken into account in any decision to change the ERLs.

25 The Working Group believes that a formal reduction in the upper ERL would not only reduce the maximum risk to which individuals could be exposed, but would also underline the message that stable iodine prophylaxis is a low risk countermeasure with the potential for large benefits. In the UK, NRPB has the statutory responsibility for advising on ERLs. The Working Group therefore recommends that NRPB considers reducing the upper ERL for stable iodine prophylaxis to 100 mGy averted thyroid dose from inhalation. In view of the higher risk to children compared with adolescents and adults, the Working Group recommends that the upper ERL for iodine prophylaxis should not be used as the planning basis for children aged under ten years.

**Reduction of the lower ERL for stable iodine prophylaxis**

26 NRPB has recommended that detailed emergency planning in the UK should generally be based on its lower ERLs. The NRPB advice also links the countermeasures of sheltering and stable iodine; as discussed in paragraphs 21–22, the Working Group recommends maintenance of this link. For these reasons, advice to reduce the lower ERL for stable iodine prophylaxis, eg to the level proposed by WHO, could have far-reaching practical consequences. It is, therefore, important to consider carefully all the implications (both benefits and costs) that such a reduction would have. The following two key issues have to be addressed.

- (a) How do the benefits expected by WHO for reducing the IL for children to 10 mGy thyroid dose compare with the benefits that would be obtained in the UK?
- (b) What are the practical consequences of implementing such a change?

**Expected benefits**

27 The Working Group has identified three factors that lead it to conclude that the benefit to be obtained in the UK, from a reduction in the lower ERL to 10 mGy thyroid dose for a child, is likely to be less than that assessed by WHO in the development of its guidance to all countries.

28 The revised WHO advice is provided in the context of the single recommended IL of 100 mGy thyroid dose for all age groups, given in the Basic Safety Standards (AEA, 1996). The Working Group considers that 100 mGy thyroid dose should not be used as a planning basis for iodine prophylaxis for children aged under ten years. However, in the UK, NRPB recommends that emergency planning should generally be based on its lower ERLs; for iodine prophylaxis, this is currently 30 mGy thyroid dose to a child.

Whilst a reduction of the lower ERL to 10 mGy thyroid dose would undoubtedly provide some measure of additional protection, the expected benefit of the reduction is clearly substantially less than that expected by WHO in the context of the ILs given in the Basic Safety Standards.

- 29 The Working Group also notes that the revised WHO guidance is strongly based on data from Belarus, the Russian Federation and the Ukraine (BR&U). Whilst the increased incidence of childhood thyroid cancers in BR&U is clearly large, with those aged under three years at the time of the accident showing the greatest increased incidence, this is mainly the result of the very large collective thyroid dose received by these children as a result of consuming locally produced contaminated milk. It also seems likely that these children experienced relatively higher uptake of ingested radioiodine by the thyroid gland compared with children in the UK, owing to a general dietary deficiency of iodine in BR&U [iodide dietary supplementation had been terminated approximately ten years before the accident (UNSCEAR, 2000)]. In the UK, provided the planned restrictions on food were implemented promptly, intakes of radioiodine, and therefore thyroid doses, even following an accident on the scale of Chernobyl, would be very much smaller than those estimated for the BR&U children. These exposures would be dominated by inhalation and, consequently, the area over which prophylaxis was required would be relatively local to the accident site. This means that, in terms of reduced incidence of thyroid cancer in children, reducing the lower ERL for iodine prophylaxis to 10 mGy thyroid dose would obtain less benefit in the UK than would have been the case in BR&U.
- 30 The Working Group recognises the need for emergency planning to consider the needs of all the local population, not just those most at risk from exposure to the release. In particular, at whatever value the ERL is set, emergency planning should consider the needs of those for whom implementation of countermeasures is not indicated, particularly those just outside a countermeasure boundary. The Working Group recommends that care is taken to avoid a sharp geographical division between the provision of countermeasures and 'life as normal'. In the context of the lower ERL for stable iodine prophylaxis, this means that planning should not be rigidly defined by the exact level of dose, but should be flexible to allow for other factors, particularly demographic factors. This, in itself, is likely to result in the provision of stable iodine prophylaxis at levels of dose below that of the lower ERL in areas of high population.

#### Practical consequences

- 31 Summaries of the UK emergency planning arrangements have been published (HSE, 1994; Home Office, 1997) and a revised document, reflecting implementation of the new Radiation (Emergency Preparedness and Public Information) Regulations (HSE, 2001), is currently being prepared by the Health and Safety Executive. The Working Group asked a subgroup of its members to investigate the likely consequences of changing these arrangements to accommodate a reduction in the lower ERL for stable iodine prophylaxis. The following paragraphs summarise the findings of that subgroup.
- 32 In the UK, detailed emergency plans are prepared for prompt implementation following an accidental release of radioactivity off-site. The existence of these plans does not preclude a more widespread response, eg if the release becomes prolonged or is much larger than envisaged in the planning. Indeed, each nuclear site is also required

to have outline emergency plans for such contingencies. However, the detailed plans ensure that those at risk of the highest exposures are given appropriate priority.

33 If the lower ERL for stable iodine prophylaxis were reduced then the area required to be covered by the detailed emergency plan (the DEPZ, or detailed emergency planning zone) would generally increase. For remote sites, the additional number of people included might not be large, but for some more highly populated areas, or areas with large influxes of seasonal visitors, the additional population could number tens of thousands. For stable iodine prophylaxis to be effective against inhalation, it must be administered within a few hours of the inhalation. Clearly, there is a trade-off between the number of people to whom stable iodine tablets are issued and the promptness with which they can be administered: enlarging the DEPZ will not inevitably increase the overall level of protection achieved. The framework established for responding to an emergency must allow flexibility to tailor the response to the specific circumstances of the accident, and so to ensure that those most at risk are given priority in protection.

34 Increasing the DEPZ will also result in increased financial and societal costs. Increased costs would arise from the need to comprehensively revise and reissue emergency plans. Furthermore, to avoid unnecessary concern, additional costs would need to be incurred in explaining to the public that nuclear facilities had not become less safe, rather there had been a scientific reassessment of the benefits and side effects of stable iodine prophylaxis. These increases in financial and societal costs need to be balanced against the expected increase in health protection that lowering the ERL for stable iodine tablets would achieve.

#### Summary

35 In summary, the Working Group concludes that adoption, in the UK, of the lower ERL for stable iodine prophylaxis currently recommended by NRPB represents a lifetime risk to a child of thyroid cancer of around 1 in 2500 (with uncertainty ranging from around 1:1000 to around 1:10 000). Whilst a reduction of the lower ERL to the WHO recommended value of 10mGy would undoubtedly provide some additional protection to children who would currently not receive prophylaxis and would probably also provide some societal reassurance, this benefit would need to be weighed against the detrimental consequences of changing existing emergency plans and of a possible reduction in protection resulting from delays in administering the tablets to those most at risk in highly populated areas.

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#### REVIEW OF OTHER PREVIOUS RECOMMENDATIONS

36 The 2nd Working Group has reviewed the other recommendations made by the 1st Working Group.

#### Dosage and tablet size

37 The 1st Working Group recommended that stable iodine be administered at the age-related dosages given in Table 1. It further recommended that tablets should contain 50 mg iodine. This represented the best compromise between avoiding adults taking large numbers of tablets and the practicality of subdividing tablets for younger age groups.

Age group	Equivalent mass of iodine (mg)
Adults (including pregnant and lactating women) and adolescents aged 13–16 years	100
Children aged 3–12 years	50
Children aged 1 month – 3 years	25
Neonates (birth – 1 month)	12.5

TABLE1 *Dosages of stable iodine as recommended by the 1st Working Group in 1991*

- 38 In its revised guidance in 1999, WHO retains its earlier advice on the age-related dosages to be administered (WHO, 1989). These are the same as those recommended by the 1st Working Group.
- 39 The 2nd Working Group concludes that there is no evidence to suggest a change to the dosage previously recommended. However, it notes the vulnerability of neonates in the first few days of life to excessive dosages of iodine. Therefore it recommends that all neonates administered stable iodine be closely monitored by their doctors for a few weeks following administration.
- 40 The 2nd Working Group also notes the potential for ambiguity on the division between the age groups: it recommends that neonates be re-defined as 'birth – under 1 month' and the younger child group be re-defined as '1 month – under 3 years'.

#### Stocks

- 41 The 2nd Working Group notes that the revised WHO guidance on the maintenance of stocks of stable iodine tablets is very similar to that recommended by the 1st Working Group. It therefore broadly endorses this advice. The Working Group has been advised that large stocks of stable iodine are currently held in the UK, distributed between locations close to licensed nuclear sites and central locations (it was informed that the UK currently holds over two million tablets). In the event of a UK accident, local stocks would be used within the DEPZ. However, in the event of a very large accident necessitating widespread administration, stocks held for other nuclear sites and those held centrally could all be mobilised.
- 42 The 2nd Working Group wishes to amplify the 1st Working Group's advice with regard to repeat administration. For many accident scenarios, the Working Group was advised that it was unlikely that the inhalation exposure would last for more than one day. If a release occurred which lasted for longer than one day, then, if practicable, the preferred response should be evacuation, rather than a repeat dose of stable iodine. Therefore the Working Group recommends that, in general, local stocks should be sufficient to provide for a single administration of stable iodine to the exposed population. Where plant assessments and local circumstances indicate the need to plan for more than one day's administration, then sufficient stocks should be held to enable this.

#### Pre-distribution

- 43 Pre-distribution of stable iodine tablets to households/centres prior to an accident occurring has both potential benefits and drawbacks. The main potential benefits are:
- promptness of administration (ie no need for distribution 'on the day'),
  - no need for sheltering individuals to leave shelter,
  - no need to expose emergency workers, if alternative means of alerting the population to the need for stable iodine are found.

The main potential drawbacks are:

- (a) tablets not readily located by individuals when needed,
- (b) distribution to transient populations or newcomers,
- (c) unintended ingestion by children,
- (d) need for individuals to cease sheltering, if tablets are held at local centres,
- (e) difficulty of access to tablets held at local centres if accident occurs when the centre is closed.

44 The Working Group is concerned that responsibility for protection should be clearly identified with the relevant response agencies: the use of pre-distribution of stable iodine tablets to assist a prompt response should not reduce the perceived responsibility of those agencies for ensuring appropriate protection of the exposed population.

45 The Working Group recognises that limited pre-distribution already takes place in the UK, and has been found to work well for specific circumstances, particularly in areas where prompt distribution on the day would be difficult to achieve. In view of this, but also mindful of the potential drawbacks of pre-distribution, the Working Group advises that limited pre-distribution may form the best means of protection in some circumstances. However, it cautions against widespread pre-distribution to individual households.

#### **Chemical form**

46 As indicated in paragraph 16, the Working Group concludes that there are no medical reasons for choosing between potassium iodide and potassium iodate. It understands that the 1st Working Group advised on the use of potassium iodate because of its expected longer shelf-life. However, the modern preparations of potassium iodide stocked elsewhere in the world have equally long shelf-lives as the iodate form. The Working Group questions the availability of good evidence to support the concerns expressed by WHO about the iodate form and notes that both forms are equally soluble. It therefore advises that there are no reasons to differentiate between the iodide and iodate forms of stable iodine, on medical grounds.

47 It should be recognised that the iodide and iodate forms have different iodine equivalents: the amounts of each form required to provide the recommended dosages of iodine are given in Table 2.

48 The Working Group has been informed that the current UK licence for manufacturing stable iodine tablets only covers the iodate form. It feels it is beyond its remit to advise DH specifically on whether the existing licence should be extended to cover production of both chemical forms. However, it was also informed of concerns by some nuclear operators over the adequate supply of future stocks. The Working Group wishes to emphasise the importance of ensuring the availability of adequate stocks at all times. It recommends that DH should review the future provision of stocks and suggests that DH consider whether additional licences or allowing the importation of iodide tablets manufactured overseas would facilitate this.

49 Owing to the vulnerability of neonates in the first few days of life to large dosages of iodine, the Working Group recommends that all hospitals with maternity units, either in the detailed emergency planning zone around nuclear sites or serving the area of these zones, should be equipped to provide accurate dosages of stable iodine in solution. This

Age group	Equivalent mass of iodine (mg)	Potassium iodate (mg)	Potassium iodide (mg)*
Adults	100	168.9	130
Children aged 3 – 12 years	50	84.4	65
Children aged 1 month – under 3 years	25	42.2	30–35
Neonates (birth – under 1 month)	12.5	21.1	15

TABLE2  
Recommended dosages for potassium iodate and potassium iodide

\*These values, taken from WHO (1989), are rounded.

means that such hospitals should stock iodine crystals in the form of either potassium iodide or potassium iodate, together with a suitable formulation depending on the salt form available and a method of preparation.

#### **Purchase by the public**

- 50 The Working Group recognises that there are no medical grounds for prohibiting the sale of stable iodine tablets to the public. Therefore, if a pharmacy were to stock them, it would not advise against the pharmacy selling them to the public. However, the Working Group is concerned that provision of stable iodine tablets through sale should not form part of emergency plans. If an emergency plan requires the provision of stable iodine tablets then these should be made available to all those needing them, free-of-charge and on an appropriately prompt timescale.

#### **Off-site emergency staff**

- 51 If emergency staff are requested to assist the implementation of countermeasures to protect the public, then they may also be exposed to the inhalation of radioiodine. Therefore the Working Group recommends that all emergency staff should be given stable iodine tablets prior to entering an area where they are likely to be exposed to inhaled radioiodine.

### **REVIEW OF PATIENT INFORMATION LEAFLET**

- 52 The Working Group was informed about concerns that the Patient Information Leaflet may be worded in a manner that is confusing to members of the public, particularly in an emergency situation. However, it was also informed that the leaflet and wording used is a legal requirement, with which the current wording fully complies. The Working Group reviewed the Patient Information Leaflet and wishes to make one specific recommendation with respect to it. At present, this leaflet specifies that one half tablet be given to neonates. One half tablet is twice the dosage recommended for neonates up to one month old. Since the tablets can readily be divided into quarters, and, considering the sensitivity of neonates to large dosages of iodine (see paragraph 39), the Working Group recommends that the Patient Information Leaflet be revised to specify that one quarter tablet be given to neonates.
- 53 The legal requirement is for one Patient Information Leaflet to be included in each box of tablets. Since boxes are opened and the required numbers of tablets distributed to each individual and household, the Working Group notes that it would be possible for a separate leaflet to be provided to the public at the time of emergency distribution.

**Leaflet distributed to the public**

54 The Working Group recognises that it is beyond its remit to recommend to DH the format for a leaflet suitable for distribution to the public at the time of an accident. However, the Working Group has considered the advice such a leaflet might contain. This might usefully include:

- (a) why taking the tablet is necessary,
- (b) a clear statement of the mass of iodine contained in each tablet,
- (c) who should take the tablets,
- (d) the number of tablets each age group should take,
- (e) the method of taking the tablets,
- (f) when to take the tablets,
- (g) the priority for prompt treatment of children,
- (h) side effects,
- (i) whether there is a need to see a doctor afterwards.

**Other information provision**

55 The Working Group recommends that the appropriate authorities give consideration to the planned provision of relevant advice to other groups needing information on stable iodine after an accident, in particular to GPs. Possible means of disseminating this information are: the national poisons database, TOXBASE; the NHS website; and production of a separate information leaflet for GPs.

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**SUMMARY OF MAIN RECOMMENDATIONS AND CONCLUSIONS**

**ERLs for stable iodine prophylaxis**

56 With respect to the ERLs for stable iodine prophylaxis, the Working Group makes the following recommendations for consideration by NRPB.

- (a) The priority for emergency planning for stable iodine prophylaxis should be the protection of newborn babies (neonates), children aged under ten years, and pregnant and nursing women.
- (b) Detailed emergency plans should provide for the stable iodine tablets to be administered promptly, as the health benefit afforded reduces with increased delay in administration.
- (c) It is not necessary to move to a system of age-related ERLs in the UK, provided that the lower ERL adopted is appropriate for children aged under ten years and neonates, and that the relevant planning emphasises the priority in administration to be afforded to these age groups.
- (d) The combination of sheltering (or evacuation) with stable iodine prophylaxis within UK emergency planning forms an important element in the provision of overall protection. Therefore, the existing link between the ERLs for sheltering and stable iodine prophylaxis should be retained.
- (e) Following a reactor accident, the ingestion of contaminated milk is potentially the greatest thyroid exposure pathway. Provided appropriate food restrictions are put in place promptly to protect children against this exposure pathway, it is appropriate

for the ERLs for stable iodine prophylaxis to be compared with expected doses from inhalation only. Otherwise it is the sum of the expected doses from inhalation and ingestion that should be compared with the ERLs.

- (f) Consideration should be given to reducing the upper ERL for stable iodine prophylaxis to 100 mGy averted thyroid dose from inhalation. This would retain flexibility for planning and response for the administration of stable iodine to adults, but signals the fact that stable iodine prophylaxis has now been demonstrated to have minimal side effects.
- (g) The administration of stable iodine tablets to children aged under ten years and neonates should generally be planned at the level of the lower ERL. The Working Group considers that the upper ERL is too high for adequate protection of these age groups.
- (h) The lifetime risk to a child, exposed to 30mGy thyroid dose (the currently recommended lower ERL), of developing thyroid cancer is in the range 1: 1000 to 1 : 10 000.
- (i) A reduction of the lower ERL to the WHO recommended value of 10mGy would undoubtedly provide additional protection to children who would currently not receive prophylaxis. However, in determining whether to reduce the lower ERL, this benefit would need to be weighed against the detrimental consequences of changing existing emergency plans – for example, a possible delay in protection for those most at risk resulting from administration of stable iodine tablets to a larger population.
- (j) NRPB should continue to review the risk estimates given here for internal exposure of the thyroid to radioiodine, in the light of future data on the incidence of thyroid cancer in those exposed in Belarus, neighbouring parts of Russia and northern Ukraine.
- (k) The provision of appropriate information and support for those not receiving stable iodine prophylaxis should be considered as part of emergency planning.

The Working Group invites NRPB to review its advice on ERLs for stable iodine prophylaxis on the basis of these points, as elaborated in the relevant paragraphs.

#### **Iodine tablets**

57 The Working Group recommends that the age-related dosages of iodine and the tablet sizes recommended by the 1st Working Group are still appropriate for use in the UK. These are set out in Table 2. In addition, the Working Group advises the following.

- (a) There are no medical grounds for preferring the iodate form over the iodide form.
- (b) The pre-distribution of stable iodine tablets can be helpful in specific circumstances, but widespread pre-distribution to individual households is not advised.
- (c) DH should review the future provision of adequate tablet stocks.
- (d) All hospitals with maternity units, either in a detailed emergency planning zone around a nuclear site or serving the area of these zones, should stock iodine crystals for the preparation of accurate dosages of stable iodine for neonates in the first few days of life.
- (e) There are no medical grounds for restricting the sale of stable iodine tablets to the public; however, emergency plans should not rely upon voluntary purchase.

- Information provision**
- 58 The Working Group makes the following recommendations.
- (a) The Patient Information Leaflet should be revised to specify that one quarter tablet be given to neonates.
  - (b) A separate, more 'user-friendly' leaflet should be prepared for distribution to the public at the time of an accident.
  - (c) The appropriate authorities should give consideration to the planned provision of relevant advice to other groups needing information on stable iodine after an accident, in particular to GPs.
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## Appendix A

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### RISK ESTIMATES FOR EXPOSURE OF CHILDREN'S THYROIDS TO RADIOIODINE

#### NRPB advice in 1990

In 1990, when NRPB issued its advice on stable iodine prophylaxis (NRPB, 1990), a number of studies relating to medical exposure to external irradiation had been carried out and reviewed by the National Council on Radiation Protection and Measurements (NCRP) in the USA, as discussed in NRPB-R226 (Stather *et al*, 1988). The exposures had been at high doses and high dose rates (exposures in the general UK population after a nuclear accident would be expected to be at low dose rates, and mostly at low doses). It was clear that children were more radiosensitive than adults, and that females were about twice as radiosensitive as males, reflecting the difference between genders in baseline rates.

For external exposure at high dose rates, NRPB recommended the NCRP risk estimate for the raised incidence of thyroid cancer of  $2.5 \times 10^{-4} \text{ y}^{-1}$  per Gy for children. For low doses and low dose rates, NRPB recommended a factor of three reduction (Stather *et al*, 1988). NRPB further advised that 10% of all thyroid cancers would be fatal. At this time a latent period of around five years was assumed, and the above annual excess risk was assumed to be constant until the end of life. Although not quoted specifically in NRPB-R226, the low dose/low dose rate risk estimate for children exposed to external thyroid irradiation would equate to a lifetime risk of fatal thyroid cancer of around  $5 \times 10^{-4} \text{ Gy}^{-1}$ , and of thyroid cancer incidence of around  $5 \times 10^{-3} \text{ Gy}^{-1}$ .

In 1990, there were very few data on the risks from internal exposure. NRPB discussed one study of medical exposures to iodine-131, which considered nearly 10 000 adults but only 500 children and which found no excess incidence of thyroid cancer (Stather *et al*, 1988). However, the numbers of children studied were too small for the null result to be meaningful for this age group. Animal studies indicated that, at high doses and high dose rates, internal exposure tended to be less effective at producing cancer than external exposure. However, it appeared to be similar in effect at low doses and low dose rates. On the basis of these data, NRPB recommended that a factor of three reduction be assumed between the risks from external exposure and those for internal exposure, at high doses and high dose rates (Stather *et al*, 1988). Given the very limited data for exposure at low doses and low dose rates, NRPB advised the cautious assumption that the risks from external and internal exposure were equivalent. On this assumption, the low dose/low dose rate risk estimate for children exposed to internal irradiation of the thyroid by radioiodine equated to a lifetime risk of thyroid cancer incidence of around  $5 \times 10^{-3} \text{ Gy}^{-1}$ , ie the same as that for external exposure at low doses/low dose rates.

#### Review of recent data

In 1993 NRPB revised its advice concerning the extrapolation of risks from high doses/high dose rates to low doses/low dose rates (NRPB, 1993). A factor of two, rather

than of three, was recommended for the extrapolation to low doses/low dose rates. This, coupled with other minor revisions to the methodology, resulted in the estimate for the low dose/low dose rate fatal cancer lifetime risk for children exposed to internal irradiation of the thyroid by radioiodine being revised to around  $7.5 \cdot 10^{-4} \text{ Gy}^{-1}$ , and that for thyroid cancer incidence being revised to around  $7.5 \cdot 10^{-3} \text{ Gy}^{-1}$ .

In 1994 a new study of the Japanese atomic bomb survivors was published, based on external exposure cancer incidence data from 1958 to 1987 (Thompson *et al*, 1994). This found the high dose/high dose rate risk for the incidence of thyroid cancer in children exposed under 10 years of age to be  $0.44 \cdot 10^{-3} \text{ y}^{-1}$  per Gy, which, using the 1993 NRPB assumptions, is equivalent to a lifetime risk of thyroid cancer incidence from either internal or external exposure at low doses/low dose rates of around  $13 \cdot 10^{-3} \text{ Gy}^{-1}$ . It further found that the radiation risk for those aged 10–19 years was approaching a factor of two lower than this, and that the risk to adults (20 years or over) was around a factor of twenty lower. The stochastic risk to those aged over 40 years at exposure was found to be negligible.

In 1995 a further analysis looked at a number of previous studies on risks to the thyroid from external exposure (Ron *et al*, 1995), including the study of Thompson *et al*. This combined analysis agreed with the Thompson *et al* estimates, although the age dependence found for the risk was a little less marked: a factor of about five between children exposed under 5 years of age and those aged between 10 and 14 years, and around another factor of two between teenagers and adults. Again, the risk to those exposed when over 40 years of age was found to be negligible. Only 2 cancer cases (out of nearly 700) presented earlier than five years after the exposure.

More recently, quantitative information has become available from the incidence of thyroid cancers in children, following the accident at the Chernobyl nuclear power plant in 1986. Several papers have been published providing indicative estimates for the observed risk from internal exposure to radioiodine, by children, following the accident at Chernobyl (Astakhova *et al*, 1998; Jacob *et al*, 1998, 1999, 2000; Heidenrich *et al*, 1999). None of these papers is definitive; some of them are based on geographical correlations, while the uncontrolled nature of the exposures means that detailed case-control studies with accurate dose estimates are difficult to achieve. Moreover, the short half-life of the dominant radionuclide, iodine-131, means that it is unlikely that the uncertainties surrounding the dose estimates will be refined in the future. On the basis of these studies the following interim conclusions may be drawn.

- (a) The age dependence for internal exposure is not dissimilar to that found for external exposure.
- (b) The lifetime risk to children of thyroid cancer incidence from internal exposure at low doses and low dose rates may be as much as equal to that from external exposure at low doses and low dose rates.
- (c) For children up to 10 years of age, females show greater radiosensitivity than males by factors of 1.5–1.7 (Astakhova *et al*, 1998; Jacob *et al*, 1999).
- (d) The uncertainty on these thyroid cancer risk estimates for childhood exposure is around a factor of 2–5.

In conclusion, the risk estimate recommended by NRPB in 1990 for internal exposure of children to radioiodine at low doses and low dose rates may have been

underestimated by a factor of two to three for children. This variation is within both past and present estimates of uncertainty surrounding the risk estimate.

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## Appendix B

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### RISKS FROM THE ADMINISTRATION OF STABLE IODINE

#### UK advice in 1990

The 1st Working Group (UK Working Group, 1991) advised that two groups of people were known to be at risk: those being, or previously, treated medically for thyrotoxicosis and those with asymptomatic nodular goitre or latent Graves' disease. The 1st Working Group noted that the first group would be under medical supervision, and so any detrimental consequences from stable iodine should be quickly remedied. Those in the second group, by definition, would not be known to have these conditions. However, the 1st Working Group estimated that the number of people in the UK at risk in this way was small, since the UK population has adequate sources of dietary iodine.

The 1st Working Group also noted that there was 'no clear scientific evidence of an increased risk of inducing hyperthyroidism from receiving the recommended dose' of stable iodine and recognised 'that further information (was) needed on this topic'.

Finally, the 1st Working Group considered the optimum chemical form for the administration of stable iodine. It concluded that there was no obvious benefit from the use of potassium iodide over potassium iodate, and so recommended that the UK retained the iodate form.

#### Review of recent data

Following the accident at Chernobyl, the Polish authorities advised a single dose of potassium iodide (KI)\* be given to children and pregnant and lactating women. In the event 10.5 million doses were administered to children<sup>†</sup> and 7 million to adults (many of them neither pregnant nor lactating women) (Nauman and Wolff, 1993). No serious side effects were seen in children, although gastrointestinal effects and minor skin rash were reported. Of those infants who received 15 mg potassium iodide within two days of birth, 12 (0.37%) showed a transient increase in serum thyroid stimulating hormone (TSH) combined with a decrease in serum-free thyroxine (T<sub>4</sub>). This transient effect had resulted in no known consequences to 1993. Among the adults, only two severe adverse reactions were seen, both in persons with known iodine allergy.

In its recent guidance, WHO concludes that the incidence of severe side effects from a single dose of iodine is less than  $10^{-7}$  for children, and less than  $10^{-6}$  for adults (WHO, 1999). The 2nd Working Group concludes that this is likely to be an upper estimate of the risks, because some of the transient side effects observed may not have been iodine related (eg some may have been caused by the ingestion of tincture of iodine).

The stable iodine taken in Poland was in the form of potassium iodide (or possibly tincture of iodine). The above risk estimates therefore, strictly, apply only to this chemical form (as opposed to potassium iodate). There is little or no comparative

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\* Specifically, 15 mg KI for newborns, 50 mg KI for children aged five years and under, and 70 mg KI for all others.

<sup>†</sup> Subsequent investigation determined that about 6% of those children receiving KI prophylaxis had also been administered tincture of iodine before the KI programme was initiated.

toxicity information on these two forms of iodine in human beings. Data from animals indicate that potassium iodate is slightly more toxic than potassium iodide, particularly when taken orally on an empty stomach. The Working Group concludes that the risks of adverse side effects from the administration of potassium iodate are of a similar order to those from potassium iodide.

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