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Guidelines for Iodine Prophylaxis following Nuclear Accidents

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ABSTRACT

Intervention levels for emergency response are for national authorities to decide, but the latest information suggests that stable iodine prophylaxis for children up to the age of 18 years be considered at 10 mGy, that is 1/10th of the generic intervention level expressed in the *International basic safety standards for protection against ionizing radiation and for the safety of radiation sources*.

For adults over 40, the scientific evidence suggests that stable iodine prophylaxis not be recommended unless doses to the thyroid from inhalation are expected to exceed levels that would threaten thyroid function. This is because the risk of radiation induced thyroid carcinoma in this group is very low while, on the other hand, the risk of side effects increases with age.

The latest information on the balance of risks and benefits will also need to be properly considered in the plans for any distribution and storage of stable iodine. It suggests that stockpiling is warranted, when feasible, over much wider areas than normally encompassed by emergency planning zones, and that the opportunity for voluntary purchase be part of national plans.

Keywords

IODINE – therapeutic use
RADIATION INJURIES – prevention and control
DISASTER PLANNING
THYROID GLAND – physiology
GUIDELINES

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Preface

In 1989, the WHO Regional Office for Europe published *Guidelines for iodine prophylaxis following nuclear accidents*, primarily stimulated by the Chernobyl accident. This was, however, prior to the significant increase in cases of childhood thyroid cancer, first reported in Belarus in 1991 and verified by a mission from the Regional Office in 1992.

The geographical extent of ground contamination by ^{131}I following the Chernobyl accident had not been anticipated and, due to its relatively short half-life, was not fully realized even in 1989. Now it is clear that a population of roughly 2.3 million children living in southern Belarus, northern Ukraine and the most easterly regions of the Russian Federation was exposed to significant amounts of radioactive iodine. The result, less than fifteen years after the accident, is more than 1000 cases of thyroid cancer, most probably solely attributable to this single release of radioactivity to the environment.

The decision to recommend the wide administration of stable iodine has to be taken only when there is certainty that more good will be achieved than harm. In this respect the experience of Poland, in employing stable iodine prophylaxis on a large scale (17 million doses distributed, 10 million to children) and evaluating the side effects, has been crucial in the decision to issue these Guidelines.

These Guidelines are based on a consultation with a wide range of experts in the relevant disciplines and are endorsed by three out of the four regional thyroid associations.

The sensitivity of the child's thyroid to the carcinogenic effects of radiation represents a significant public health risk in the event of exposure to radioactive iodine. With effective planning and the use of stable iodine prophylaxis, in association with other preventive measures, this risk is to a large degree avoidable.

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Foreword

In 1989, the WHO Regional Office for Europe issued *Guidelines for iodine prophylaxis following nuclear accidents* at the instigation of two Member States, Switzerland and the United Kingdom. These Guidelines were based on a Workshop discussion and comments by specialized reviewers and provided authoritative and practical guidance on all aspects of iodine prophylaxis as it applies to nuclear emergencies.

In 1991, the first indications of a marked increase in childhood thyroid cancer became apparent in Belarus and then in the Russian Federation and Ukraine. These countries were closest to the Chernobyl accident. When the seriousness of this increase became clear beyond doubt, and the results of the administration of stable iodine to the child population of Poland immediately after the accident, were available, WHO convened a small expert group *(1)* to advise on the need to revise the Guidelines. As a result, two consultants (Dr Wendla Paile and Mr Leif Blomqvist) were asked to prepare a revised document based on the views expressed at that expert group meeting. Following consultation with WHO headquarters in Geneva and the International Atomic Energy Agency (IAEA) in Vienna, several expert reviewers were consulted *(2)*. The comments were reviewed by the consultants and the WHO and IAEA secretariats and the document accordingly amended. A final formal review of the document took place in association with the annual American Thyroid Association meeting in Portland, Oregon, USA in September 1998 *(3)*. Each of the four regional thyroid associations were invited to nominate two experts and the IAEA nominated two additional participants. Following the Oregon meeting, the regional thyroid associations were invited to endorse the document and three – the ETA, the OATA and the LATS – agreed to do so.

Stimulated by the reports of increased thyroid cancer the research community has made much progress in understanding the nature of radiation-induced thyroid cancer and its dependence on age at exposure. It became clear that in order to protect public health it would be necessary to intervene at lower doses for children and young people aged up to and including 18 years at exposure than for young

adults. In contrast, older adults would have little benefit from iodine prophylaxis to avert comparatively low doses, while being subject to higher risks of side effects. The revised document, therefore, departs from its predecessor in giving advice on how to obtain optimal protection of public health in the application of the presently recommended generic intervention level of 100 mGy, applied independently of age, to the practical circumstances where young and older adults are potentially exposed to radioactive iodine.

The present document, therefore, provides an authoritative update to the advice issued by the WHO Regional Office for Europe in 1989.

The aims and objectives of the document are:

- from the public health perspective:
  - to summarize the current assessment of the benefits and risks of stable iodine prophylaxis to block the uptake by the thyroid gland of radioactive iodine released to the environment in accidents and emergencies;
  - to provide information on appropriate dosage and contraindications for the administration, as a public health measure, of stable iodine to various population groups;
- from the emergency preparedness perspective:
  - to aid the planning for such an administration in an emergency; and
  - to give guidance on the practical aspects of the storage and distribution of stable iodine.

The potential readership of the document includes:

- public health authorities and physicians at national and local levels
- nuclear emergency planners, emergency management personnel
- emergency aid administrators
- civil defence personnel.

The purpose of this document is to make available the latest information on the use of stable iodine prophylaxis in the context of radiation protection of the thyroid, and in particular as part of the emergency response preparedness for nuclear accidents. It should be

stressed that it has no implications for the routine medical use of radioiodine in diagnosis and treatment of thyroid disorders.

In issuing this document, the World Health Organization welcomes comments from experts and institutions for further advice for future updating of the document.

1. Introduction

Despite rigorous safety systems, there remains a finite probability that an accident can occur in a nuclear reactor that can lead to the fuel in the core overheating or melting. If such an event were to occur, there is a chance that radioactive fission products may be released to the environment. The potential radiation exposure of the population will be influenced by the amounts of various radionuclides released, by the meteorological conditions affecting the dispersion and deposition of the released radioactive material, by human and environmental factors, and by the effectiveness of any protective actions taken.

Protective actions are taken in order to (1) prevent so-called deterministic effects (hypothyroidism, for example) from high levels of radiation exposure, and (2) reduce the risk of stochastic effects (for example, thyroid cancer and benign nodules) from exposure to levels as low as reasonably achievable. However, during and shortly after the onset of an accident, there are great uncertainties concerning the levels and extent of potential radiation exposure of the population. In order to protect people close to the reactor effectively from deterministic effects, precautionary protective actions are usually planned to be implemented for populations in the immediate vicinity, that is up to about 5 km, based on plant conditions and before any potential release occurs. If a release has begun, measurements can be taken that can help to limit the estimated risk to the population; nevertheless, it is extremely difficult to predict accurately the time variation and length of the release from the damaged reactor, its dispersion and subsequent doses to the population at greater distances. After the release stops, measurements of deposition and concentrations of radioactive materials in foodstuffs can be taken to confirm accurately the basis for any future protective actions.

In order to be able to respond rapidly, consistently and appropriately, national authorities will have an emergency plan. This plan will take into account the potential magnitude and likelihood of releases, and distances from reactors. It sets out responsibilities and authorities for decision-making and for protective actions, and also lays down so-called intervention levels for the various protective actions, which can be used in preparing detailed emergency response plans. The various protective actions for which detailed plans are made include sheltering

and evacuation, which can reduce both the external and internal radiation exposure of the population, food and agricultural countermeasures to restrict ingestion of radioactive material, as well as stable iodine prophylaxis.

Isotopes of iodine (^{131}I, ^{132}I, including that arising from the decay of tellurium-132 (^{132}Te), ^{133}I; see Annex 1 for table of half-lives) are likely to be important components of the release from a severe accident. Radioactive iodines can give rise to both external exposure and internal exposure (from inhalation and ingestion). Stable iodine prophylaxis is a protective action for which preparedness arrangements can be made as part of the overall emergency response plan, and that can protect specifically against internal exposure from inhalation and ingestion of radioiodines.

It should be noted that the term "iodine prophylaxis" refers to the blocking of the uptake of radioiodine after nuclear accidents and not to the correction of dietary iodine deficiency.

The decision to plan for short-term prophylaxis against radioactive iodine should not be influenced by dietary iodine status. Dietary iodine deficiency increases the uptake of radioactive iodine in the thyroid. However, a normal iodine status would not reduce the need for prompt stable iodine prophylaxis in the event of a nuclear emergency. While dietary iodine supplementation in iodine-deficient areas is important in its own right, it does not eliminate the need to plan for stable iodine prophylaxis.

2. Radiation risk from radioactive iodine

2.1 Exposure to radioactive iodine

The radioactive isotopes of iodine, along with other radionuclides, give rise to external radiation exposure from radioactive material present in a radioactive cloud, deposited on the ground and on skin and clothing. In the case of the radioactive isotopes of iodine, a major concern is the internal radiation exposure following incorporation and uptake in the thyroid. This will occur through inhalation of contaminated air and ingestion of contaminated food and drink.

Absorption through the skin is a possible route, but negligible in comparison with inhalation.

2.2 Deterministic and stochastic effects

Deterministic effects from thyroid exposure are hypothyroidism and acute thyroiditis. Stochastic effects from thyroid exposure are thyroid cancer and benign thyroid nodules.

The selective and rapid concentration and storage of radioactive iodine in the thyroid gland results in internal radiation exposure of the thyroid, which may lead to an increased risk of thyroid cancer and benign nodules and, at high doses, hypothyroidism. These risks can be reduced or even prevented by proper implementation of stable iodine prophylaxis.

Hypothyroidism is caused by a radiation dose of the order of more than several Gy to the thyroid. A dose that large could, in practice, be incurred through inhalation only near the point of the accidental release. Because exposures from other radionuclides are also likely to be large in such cases, plans will usually include options to evacuate and/or shelter the population, and stable iodine can be a useful adjunct to these actions.

In regions where only the likelihood of stochastic effects is a cause for concern, stable iodine prophylaxis should be considered for sensitive population groups if potential exposure to radioactive iodine by inhalation or exposure by ingestion is expected to approach the reference levels given in Table 1, and cannot be prevented by sheltering or food and milk control. In severe accidents such situations may occur in areas quite far from the accident site.

Intake through ingestion of contaminated food, particularly milk, begins after deposition and transfer to the food chain. In the absence of any countermeasures, ingestion is likely to be the main route of internal radiation exposure to radioactive iodine. The exposure is likely to continue for a longer period, cover a wider area and affect a larger population than exposure by inhalation.

2.3 Experience from the Chernobyl accident

Evidence of a marked excess of thyroid cancer in children exposed to the fallout from the Chernobyl accident has been established *(1–10)*. In the most affected area in Belarus, the yearly incidence has risen close to 100 per million children, which is more than 100-fold compared to the situation before the accident. It is now generally accepted that this excess has resulted from exposure to the radioactive iodine released in the accident. The largest part of the dose to the thyroid was caused by ^{131}I although the shorter lived isotopes of iodine and ^{132}Te may have contributed significantly to the inhalation dose in some instances.

Table 1. Reference levels for different population groups for consideration in planning stable iodine prophylaxis[a]

Population group	Exposure pathways to be considered	Reference levels
Neonates, infants, children, adolescents to 18 years and pregnant and lactating women	Inhalation (and ingestion[b])	10 mGy[c] avertable dose to the thyroid
Adults under 40	Inhalation	100 mGy[c] avertable dose to the thyroid
Adults over 40 years	Inhalation	5 Gy[d] projected dose to the thyroid

Notes
[a] These idealized levels do not take into account the practicalities involved in planning to respond to an accident involving many radionuclides in unknown quantities in real time. For this reason, a generic intervention level of 100 mGy has been specified in the Basic Safety Standards. Nevertheless, this does not preclude the need to consider the practicality of planning to implement iodine prophylaxis for specific age groups.
[b] Ingestion of milk by infants where alternative supplies cannot be made available.
[c] Adherence to these values would ensure that doses for all age groups would be well below the threshold for deterministic effects.
[d] Intervention for this group is undertaken to ensure prevention of deterministic effects in the thyroid. 5Gy is the recommended limit for deterministic effects given in the Basic Safety Standards.

Following the Chernobyl accident there were several thousands of children who accumulated a dose to the thyroid of several Gy.

Nevertheless, most of the children that have developed thyroid cancer were exposed to an estimated dose to the thyroid of less than 300 mGy *(8)*. There has been an excess thyroid cancer incidence even in areas where the mean dose to the thyroid in children was estimated at 50–100 mGy *(9)*. The increase in incidence has been documented up to 500 km from the accident site. This is understandable in terms of the wide area affected by radioiodine and therefore the large number of children exposed.

The Chernobyl accident has thus demonstrated that significant doses from radioactive iodine can occur hundreds of kilometres from the site, beyond emergency planning zones. A sharp distinction in the requirements for stable iodine prophylaxis based on distance from the accident site cannot be made. For example, few regions in Europe are situated so far from a nuclear reactor as to preclude any potential need for stable iodine prophylaxis against inhaled or ingested radioactive iodine.

Another important insight gained from the Chernobyl accident concerns the side effects from stable iodine. In Poland stable iodine, as single doses, was given to 10 million children *(11)*. No serious side effects were seen, though gastrointestinal effects and minor skin rash were reported. Of newborn infants receiving 30 mg potassium iodide in their first two days of life, 0.37% (12 infants) showed a transient increase in serum thyroid stimulating hormone (TSH), combined with a decrease in serum free thyroxine (T4). This transient thyroid inhibition has had no known consequences to date. Seven million adults took stable iodine although it had not been recommended. Among these, only two severe adverse reactions were seen, both in persons with known iodine allergy. In summary, the incidence of severe side effects from a single dose of iodine was less than 1 in 10 million in children and less than 1 in a million in adults.

2.4 Estimates of cancer risk

Risk estimates for thyroid cancer attributable to radiation exposure have been made for populations exposed to external irradiation. According to the National Council on Radiation Protection (NCRP) *(12)*, the excess absolute risk (EAR) is 2.5×10^{-4}/Gy per year for persons exposed under the age of 18. For adults, the risk per year is taken as half this value.

The lifetime risk for adults would be 1/4 of the risk for children, because of the smaller number of years at risk.

The most current estimate, based upon a pooled analysis including five cohort studies, gives an EAR of 4.4×10^{-4}/Gy per year for persons exposed before the age of 15 *(13)*. The study indicated the relative risk to be heavily dependent upon age at exposure, younger children being at significantly higher risk than older ones. From the Lifespan Study of atomic bomb survivors in Hiroshima and Nagasaki it is known that little risk is indicated after the age of 20 and virtually none for exposure after the age of 40 *(14)*.

While internal exposure to radioactive iodine in medical use has not been shown to cause thyroid cancer in adults, the clinical experience in the case of young children is very limited. The experience from the Chernobyl accident shows the risk to be real. While the thyroid sensitivity in adults to both external radiation and ^{131}I seems to be minimal, or even absent in the elderly, sensitivity in young children is high.

According to a recent dose–response analysis based on combined data from Belarus, Ukraine and the Russian Federation, the three countries most affected by the Chernobyl accident, the risk for those aged 0–15 at exposure was 2.3×10^{-4}/Gy per year with 95% confidence intervals that overlap those of the pooled analysis (13) *(9)*. More recently an analysis of time trends in thyroid cancer incidence in Gomel in Belarus *(10)* concludes that risk estimates from external exposure are consistent with risk estimates from Gomel assuming that the increase in excess cases reaches a plateau soon. If this risk persists unchanged for 40–50 years, the lifetime risk of cancer would be about 1%/Gy.

For public health purposes in emergency planning and response, it is, therefore, prudent to assume equivalence of carcinogenic effect between X-rays and radiation from ^{131}I.

Radiation-induced thyroid cancer is not a trivial disease, although it has a very low mortality if properly treated. It causes significant morbidity and the treatment is lifelong, putting a considerable burden on the health care system.

3. Stable iodine prophylaxis as a protective measure

3.1 The rationale for administration of stable iodine

Stable iodine administered before, or promptly after, intake of radioactive iodine can block or reduce the accumulation of radioactive iodine in the thyroid.

Intake of radioactive iodine by inhalation begins when the radioactive cloud arrives at a location and continues during the passage of the cloud. Action to implement stable iodine prophylaxis, and thereby reduce the dose to the thyroid, will be required promptly. The decision will most probably have to be made in a situation when reliable data for calculating the potential dose to the thyroid are not available.

Stable iodine could also be used as prophylaxis against ingested radioactive iodine from contaminated food. However, because the risk of exposure from ingestion of iodine will remain for a longer time, iodine prophylaxis will also be required for a longer period of time, leading to a need for repeated doses. The side effect rate from multiple doses would be higher, but the frequency is not known. It is probably low in children but may be significant in adults, especially in areas with dietary iodine deficiency.

Exposure by ingestion can also be considerably reduced by agricultural countermeasures such as removing grazing animals from contaminated pasture or by the imposition of appropriate controls on agricultural products. In general, food controls would be easier to implement and more effective in the long term in reducing the collective dose than stable iodine prophylaxis. Therefore, agricultural and food control measures are preferable to repeated doses of stable iodine.

3.2 Side effects from stable iodine: general considerations

Thyroidal side effects may result from stable iodine administration, especially in iodine deficient regions. There is an increased risk in

connection with thyroid disorders, such as auto-immune thyroiditis, Graves' disease and nodular goitre. Such disorders are common in the adult population and in the elderly but relatively rare in children. The risk of thyroid blocking in the newborn deserves special attention and is treated in more detail below.

Side effects in other parts of the body, such as gastrointestinal effects or hypersensitivity reactions, may occur but are generally mild and can be considered of minor importance. Dermatitis herpetiformis and hypocomplementaemic vasculitis entail an increased risk of severe hypersensitivity reactions.

The Polish experience, cited above in section 2.3, showed the risk of severe side effects from single doses of stable iodine to be minimal (less than 1 in 10 million in children and less than 1 in a million in adults). However, for repeated doses, there is no direct human experience that can be used for reliable numerical estimation of side effects.

3.3 Consideration of exposed population groups

Exposed population groups differ markedly in their risk of radiation induced thyroid cancer from a given radiation dose. Neonates, infants and small children are the most sensitive groups. The risk of side effects from stable iodine prophylaxis is also different, albeit generally small in the light of the latest experience. Because of these differences it is important to consider potentially exposed population groups separately when deciding on plans for stable iodine prophylaxis.

In general, the potential benefit of iodine prophylaxis will be greater in the young, firstly because the small size of the thyroid means that a higher radiation dose is accumulated per unit intake of radioactive iodine. Secondly, the thyroid of the fetus, neonate and young infant has a higher yearly thyroid cancer risk per unit dose than the thyroid of an adult and, thirdly, the young will have a longer time span for the expression of the increased cancer risk.

Individual radiation doses will also differ markedly within any exposed group. The intake of radioactive iodine through inhalation

will be influenced by breathing rates and intake through ingestion will be influenced by dietary habits.

In the following, the risks from radiation exposure and the risks from stable iodine prophylaxis, respectively, are examined in more detail for the various population groups.

Pregnant women

During pregnancy, the maternal thyroid gland is stimulated, especially during the first trimester. The fraction of radioactive iodine taken up by the thyroid is increased as compared to other adults. Thus, there is a greater need to protect the thyroid gland of the pregnant woman.

During the second and third trimesters, the thyroid gland of the developing fetus takes up and stores iodine in increasing amounts. Iodine passes readily across the placenta, and thus, after the first trimester, the fetal thyroid gland can be exposed to radioactive iodine through the placenta, but it can also be protected by stable iodine taken by the mother. However, the risk of blocking the fetal thyroid function by a prolonged overload of stable iodine must be kept in mind, especially in areas with inherent dietary iodine deficiency.

While there are physiological differences between the trimesters, outlined above, there is no need for a different policy of intervention, which would create substantial problems in practice. Throughout pregnancy, the number of stable iodine doses should be kept to the minimum needed to provide adequate protection against inhaled radioactive iodine. No negative consequences are to be expected after one or two doses of stable iodine. However, especially in areas with dietary iodine deficiency, prolonged dosage could lead to maternal and/or fetal thyroid blockage, with possible consequences for fetal development. It is important, therefore, that this be avoided. To protect against ingestion of radioactive iodine, which would imply repeated doses of stable iodine, appropriate food control measures such as the provision of uncontaminated milk must be given priority. If stable iodine is given late in pregnancy, there is a need to monitor the newborn for thyroid function, but this would be met by routine screening programmes already in place in most countries. Pregnant women with active hyperthyroidism must not take stable iodine because of the risk of fetal thyroid blockage.

Neonates

Newborn infants are quite likely the critical group of concern when deciding on the implementation of stable iodine prophylaxis. In the first few days of life they are at special risk both of exposure from radioactive iodine and blocking of thyroid function by an overload of stable iodine.

After birth, there is a dramatic increase in thyroid activity, lasting only a couple of days. The fraction of radioactive iodine intake that will be incorporated into the thyroid at this critical stage can be fourfold greater than for all other age groups *(15)*. On the other hand, during this period the thyroid is especially sensitive to the functional blocking caused by an overload of stable iodine. The most critical period for developing thyroid blockage lasts for less than a week, even in the premature. Even transient hypothyroidism during the critical period of brain development can result in loss of intellectual capacity *(16)*. The potential for harmful influence on neurointellectual development, however, was not confirmed in the Polish study referred to in section 2.3.

When indicated, stable iodine in the form of potassium iodide (KI) will be promptly given to all neonates. The dosage is critical. A single administration of 12.5 mg iodine (16 mg KI) should not be exceeded. If stable iodine is given, close follow-up is essential.

KI solution should be readily available in maternity hospitals. This will enable prompt and exact dosage to the critical group of the newborn still on the ward. A few days later the sensitivity for blockage of thyroid function will have decreased and dosage may be performed at home, by dividing, crushing and suspending tablets in milk or water. In infants who have been administered stable iodine in the first weeks of life, TSH levels and, if indicated, T_4 levels will be monitored and appropriate replacement therapy given.

Infants, children and adolescents (1 month to 18 years)

These groups are at high risk from exposure to radioactive iodine but at very low risk from stable iodine. The dose to the thyroid from radioactive iodine in a given situation will be higher in this group than in adults because of the smaller size of the gland, which is only partly compensated for by a smaller breathing volume. The highest dose

from inhalation, up to threefold as compared to adults, will be in children around three years old. The dose from ingestion may be several times higher compared to adults, because of the generally high consumption of milk in relation to thyroid mass in this group.
When intervention is decided upon, based on the emergency plans and predetermined operational intervention levels, stable iodine should promptly be given to all children. If intake of radioactive iodine through inhalation is prolonged, the recommended single stable iodine dose (cf. Table 2) will be repeated daily. This would most probably cause no harm. However, in children showing skin reaction to the first dosage, the stable iodine administration should not be given repeated doses.

Table 2. Recommended single dosage of stable iodine according to age group

Age group	Mass of iodine mg	Mass of KI mg	Mass of KIO_3 mg	Fraction of 100 mg tablet
Adults and adolescents (over 12 years)	100	130	170	1
Children (3–12 years)	50	65	85	1/2
Infants (1 month to 3 years)	25	32	42	1/4
Neonates (birth to 1 month)	12.5	16	21	1/8

In general, appropriate control of foodstuffs is to be given priority as the countermeasure against ingestion of radioactive iodine. In the exceptional case that this is not possible, or when it would lead to deficiency of essential nutrients such as milk, prophylaxis with daily doses of stable iodine can be continued for a few days, or even weeks, in this group, as necessary.

Lactating mothers

Iodine is actively transported to the milk. As much as 1/4 of the iodine taken by the mother may be secreted in the milk within 24 h *(17)*. An

excess of stable iodine can block the transport to a certain extent. However, if the infant is administered stable iodine, it will be protected from radioactive iodine in the milk for the next day. Therefore, stable iodine prophylaxis for lactating mothers can be decided upon by the same criteria as for other young adults, to protect the woman herself. Repeated dosage is to be avoided.

Adults under 40 years

In young adults, the risk of radiation induced thyroid cancer is low *(14)*. On the other hand, the risk of serious side effects from a single dose of stable iodine is also low. Stable iodine as a single dose can be given to this group if intervention is decided upon. The dose criteria for intervention will in principle be significantly higher than for children. It will be important that contraindications (known iodine allergy, present or past thyroid disease of any kind, dermatitis herpetiformis, and hypocomplementaemic vasculitis) be taken into consideration.

Repeated administration of stable iodine for protection against ingested radioactive iodine is not indicated in this group, as the risk of side effects will be increased. Appropriate control of food may also be easier for adults than for children. Adults could, for example, completely abstain from drinking milk during the contamination period, without fear of nutritional effects.

Adults over 40 years

The risk of radiation induced thyroid cancer in this group is probably extremely low and may even be zero *(14)*. The risk of side effects from stable iodine increases with increasing age as the incidence of thyroid diseases is higher. Stable iodine prophylaxis is not indicated for this group, unless doses to the thyroid from inhalation rise to levels threatening thyroid function, that is of the order of about 5 Gy. Such radiation doses will not occur far away from an accident site (cf. section 2.2).

4. Implementation of stable iodine prophylaxis

4.1 Intervention levels

According to the basic principles of radiological protection, intervention to protect the public should be undertaken if serious deterministic effects are projected or if there is a high individual risk of stochastic effects; and protective actions should achieve more good than harm and reduce the risk of stochastic effects to as low as reasonably achievable.

The decision to initiate stable iodine prophylaxis should generally be made on the basis of predetermined conditions specified in the emergency plans. These conditions can include the accident classification and levels of measurable quantities that will trigger response. These conditions and levels are precalculated, in part on the basis of so-called intervention levels, which in turn are specified in terms of avertable dose. The avertable dose is defined as the dose to be saved by the particular protective action; in this case, the difference between the dose to be expected with stable iodine prophylaxis and that to be expected without it. In the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources *(18)*, a generic intervention level of 100 mGy avertable dose is recommended for all age groups.

Notwithstanding the generic recommendation, it is appropriate to consider the differing risks for different age groups when developing detailed emergency plans, and also the possibility of differential administration of stable iodine prophylaxis. In this way, the greater need of children for stable iodine and the greater risk of side effects in the elderly, can be separately catered for. Emergency plans also need to complement plans for evacuation, sheltering and food control, and take into account doses to any workers involved in distribution.

As side effects from short-term stable iodine prophylaxis are now known to be minimal, the decision to plan for prophylaxis will depend mainly on the estimated social and economic costs. Provided that predistribution of stable iodine to strategic sites has taken place and iodine tablets are readily accessible, the costs will be low. Nevertheless, consideration will need to be given to the psychosocial consequences of iodine prophylaxis, both in terms of the reassurance

it may provide and any possible anxiety it may create among the population.

4.2 Balance between risk and benefit of taking stable iodine

The lifetime cancer risk for exposed children can be taken to be 1%/Gy (see section 2.4) and the risk of severe side effects from a single administration of stable iodine to be 10^{-7}. Accordingly, a risk equals benefit analysis (ignoring other factors) in averting doses as small as 0.01 mGy. In practice, this means that the risk of severe side effects can be ignored when deciding on the intervention level. Minor side effects from stable iodine prophylaxis, such as skin rash or gastrointestinal complaint, constitute no major problem.

On assuming a severe accident and applying the risk estimates for children cited in section 2.4 and the generic intervention level of 100 mGy, without regard to age group, the incidence of thyroid cancer among those most exposed might be of the order of 20–50 per million children per year. This is to be seen against the background of spontaneous childhood thyroid cancer of about 1 case per million children per year. The corresponding lifetime risk would be 0.1–0.3% for all children and even more for small children of the most sensitive age. On the other hand, applying an age-specific intervention level of 10 mGy radiation dose to the thyroid, the incidence of thyroid cancer among those most exposed might be some 2–5 extra cases per million children per year, still a several fold increase compared to the generally encountered background incidence. The corresponding individual lifetime risk would be of the order of $1–3\times10^{-4}$.

In view of the established relatively high risk of thyroid cancer among those exposed in childhood, planning for stable iodine prophylaxis for children should ideally be considered at 1/10th of the generic intervention level, that is at 10 mGy avertable dose to the thyroid. This level is also appropriate for pregnant women.

Even if an avertable dose were grossly overestimated in a real emergency, no significant health hazard would result from stable iodine administration.

It has not been possible to make a corresponding risk–benefit analysis for adults, as the carcinogenic effect from ^{131}I in adults has not so far been confirmed. For young adults, however, in the light of the low frequency of severe side effects (10^{-6}) from single doses of stable iodine, prudence argues in favour of applying the generic intervention level given in the Basic Safety Standards.

For adults over 40, the risk of radiation-induced thyroid cancer is presumed to be close to zero. For this group, the implementation of stable iodine prophylaxis is determined by the need to ensure prevention of deterministic effects. This is guaranteed by an action level of 5 Gy projected dose to the thyroid (but see section 5).

Table 1 summarizes the reference levels for different population groups for consideration in planning stable iodine prophylaxis.

5. Considerations in planning the use of iodine prophylaxis in conjunction with other countermeasures

In emergencies involving a release to the environment of radioactive iodine there is a need for an early warning and rapid response so that measures that prevent or mitigate exposure can be implemented. Such measures include evacuation, sheltering and food controls as well as iodine prophylaxis. The optimum response will often involve the combined use of these countermeasures.

It should be noted that while the other countermeasures protect against most radionuclides and external exposure, iodine prophylaxis protects only against inhaled or ingested radioiodine.

5.1 Evacuation

Evacuation means temporarily moving people out of the area predicted to be affected by the radioactive release. Evacuation is most effective when implemented before the passage of the radioactive cloud. Precautionary evacuation will pre-empt the need for stable

iodine administration, but instructions to take iodine tablets when pre-distributed should be considered in planning.

Evacuation will be decided upon primarily on the basis of plant conditions and meteorological data. However, plans should take account of the fact that persons to be evacuated may have been exposed to the radioactive cloud.

5.2 Sheltering

Advising the population to stay indoors is a relatively simple protective measure in the early phase of an accident. The decision to implement sheltering will be considered in nuclear emergency planning as a means of protection against external radiation as well as against inhalation of all radionuclides.
Inhalation of radioactive iodine from a passing cloud will be reduced to some degree by sheltering indoors with closed windows and any forced ventilation shut off, but sheltering is not completely effective in avoiding inhalation doses. Realistic dose estimates need to be taken into account in considering plans for the implementation of stable iodine prophylaxis.

It is important that planning for the simultaneous implementation of stable iodine prophylaxis be seriously considered as a supplement to sheltering plans where the expected avertable inhalation dose to the thyroid approaches those in Table 1, and for those accidents where radioactive iodine is a major component of the release.

5.3 Food control

The principal protective measures against internal exposure through ingestion are firstly, agricultural countermeasures (such as putting grazing animals on stored feed) followed by the banning of potentially contaminated foodstuffs or locally produced agricultural products. For this route of exposure or pathway, food control is generally preferable to the use of stable iodine prophylaxis.

However, withholding milk from infants and young children will have disadvantages and, in some circumstances, it may be foreseen that the rapid distribution of uncontaminated milk to infants or transfer of

animals to stored feed cannot be arranged or planned. Therefore, in considering plans for stable iodine prophylaxis for infants and young children, it is important that this issue be taken into account.

For other population groups, the removal of milk from the diet for several days is an inconvenience but this is no argument to plan for iodine prophylaxis as an alternative to food control or agricultural countermeasures.

6. Logistics of stable iodine prophylaxis

6.1 Chemical form

Stable iodine can be used either as potassium iodide (KI) or potassium iodate (KIO_3). KI is the preferred alternative, since KIO_3 has the disadvantage of being a stronger intestinal irritant *(19)*.

There is no decisive difference in shelf life between KIO_3 and KI. If storage conditions are adequate, the expected shelf life of the tablets is at least 5 years. After 5 years the iodine content may be checked and the shelf life extended, if indicated.

6.2 Formulation, storage and packaging

Stable iodine can be given in either doubly scored tablet or liquid form. Tablets have the advantage of easy storage and distribution, including predistribution. Also, stable iodine is likely to cause less gastrointestinal irritation if administered in tablet form. Tablets can be crushed and mixed with fruit juice, jam, milk or similar substance.

Tablets should be stored protected from air, heat, light and moisture. Age-dependent dosage and contraindications should be on the labelling.

Tablets packed in a hermetic alufoil and kept in a dry and cool place preserve fully their iodine content for 5 years *(20)*.

6.3 Availability, predistribution and distribution

As there is only limited time for implementation of prophylaxis, prompt availability of the tablets to individuals has to be ensured if they are to be at their most effective. In the vicinity of nuclear reactors, predistribution to households should be seriously considered, taking into account plans for evacuation and sheltering, with provision for storage in places that can be controlled by the responsible authorities. Clear instructions should be issued with the tablets, and public awareness of the procedures should be monitored on a regular basis. Medical personnel likely to be consulted by the public should be provided with more detailed information.
At greater distances from the site of release there is likely to be more time for decision-making. If predistribution to households is not considered feasible, stocks of stable iodine should be stored strategically at points that may include schools, hospitals, pharmacies, fire stations, police stations and civil defence centres. Widespread storage may be warranted at considerable distances from the potential accident site. Storage should preferably be at places where proper stock control is standard practice. Planning should consider the use of redundant distribution areas to minimize delays in implementing stable iodine prophylaxis. Due consideration should also be given to whether the benefits of stable iodine distribution outweigh the disadvantages associated with any additional exposure of responsible emergency personnel.

National authorities are advised that, because of the benefits of stable iodine prophylaxis and the generally minimal risks of side effects, voluntary purchase of iodine tablets by the general public should be allowed. However, within the framework of the overall nuclear emergency plan, the responsibility for distribution of stable iodine and instructing the public on how to use it should still be clearly assigned to the appropriate authorities.

6.4 Dosage and contraindications

For adequate suppression, the dosage scheme given in Table 2, which is based on a single dose for adults of 100 mg of iodine, is recommended.

The tablet divisions indicated in Table 2 are easy to achieve with a tablet stamped by a cross, except that the exact dosage of 1/8 tablet required for neonates is difficult to ensure. However, for neonates over 1 week of age living at home, an approximate division would be satisfactory. The most sensitive group of the newborn, those less than 1 week old, should preferably have a more exact dosage. This can be achieved with KI solution freshly prepared from crystals. It is, therefore, recommended that maternity wards keep KI in storage in crystal form.

As an alternative, tablets containing 50 mg of iodine (65 mg KI or 85 mg KIO_3) can be used, correspondingly doubling the tablet dosage indicated in Table 2. It is recognized that some iodine tablets are too small to subdivide effectively and it is recommended that tablets of sufficient size be manufactured.
The contraindications for use of stable iodine are:

- past or present thyroid disease (e.g. active hyperthyroidism)
- known iodine hypersensitivity
- dermatitis herpetiformis
- hypocomplementaemic vasculitis.

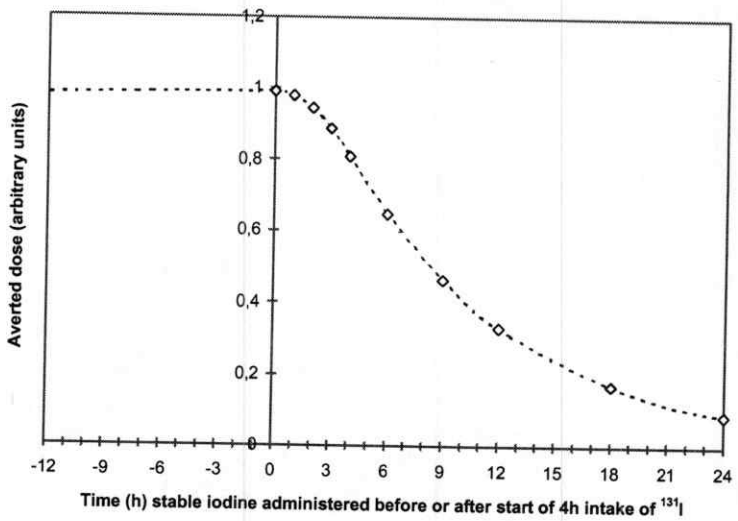
These should be clearly stated on the labelling.

6.5 Timing of administration and duration of prophylaxis

To obtain full effectiveness of stable iodine for thyroidal blocking requires that it be administered shortly before exposure or as soon after as possible. However, iodine uptake is blocked by 50% even after a delay of several hours. Fig. 1 shows the effectiveness of thyroid blocking achieved by administering stable iodine at different times before or after a 4-h exposure to radioiodine.

To protect against inhaled radioactive iodine, a single dose of stable iodine would generally be sufficient, as it gives adequate protection for one day. This may well be enough to protect from inhaled radioactive iodine present in a passing cloud. In the event of a prolonged release, however, repeated doses might be indicated.

Fig. 1. Averted dose as a function of time stable iodine is administered relative to a 4-h intake of ^{131}I for different dietary iodine intakes



In some circumstances stable iodine administration may also be practical in limiting the dose to the thyroid from ingested radioactive iodine, especially to children via the milk pathway where alternative sources cannot be found. In that case, a daily dose of stable iodine may be given for the time period needed to those children who show no adverse reaction. Repeated administrations should not be given to neonates, or to pregnant or lactating women (see section 3.2).

Due consideration should be given, in preparing emergency plans, to mitigating any adverse psychosocial reactions to the implementation of iodine prophylaxis. To avoid public concern, distribution and instructions to different age groups must be orderly and consistent. There are advantages in consulting with neighbouring countries with regard to their national policy in order to avoid discrepancies of approach, especially where reactors are close to national borders.

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Annex 1

HALF-LIVES OF THE IMPORTANT RADIOISOTOPES RELATED TO RADIOACTIVE IODINE FOUND IN FISSION PRODUCTS

Nuclide	Half-life
^{131}I	8.04 d
^{132}I	2.3 h
^{133}I	20.8 h
^{135}I	6.61 h
^{132}Te	3.26 d

Annex 2

GLOSSARY OF TERMS AND ACRONYMS

Terms

Accident	Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.
Autoimmune thyroiditis	A chronic inflammatory disease of the thyroid gland with anti-thyroid antibodies present in the blood (Hashimoto's thyroiditis). Often leads to hypothyroidism.
Avertable dose	The dose to be saved by a protective action; that is, the difference between the dose to be expected with the protective action and that to be expected without it.
Basic safety standards	A comprehensive set of standards for radiological protection and the safety of radiation sources, agreed between various international organizations, including WHO and IAEA, for international application.
Dermatitis herpetiformis	A chronic skin manifestation of gluten sensitivity (coeliac disease) with clusters of itching papules, vesicles and crusts, mostly on the knees, elbows or buttocks.
Deterministic effect	A radiation effect for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose (see also stochastic effect).
Dosage	Schedule for administration of a medical preparation (e.g. potassium iodide) in a prescribed amount.

Dose	A measure of the radiation received or 'absorbed' by a target. the quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose or committed effective dose are used, depending on the context. the modifying terms are often omitted when they are not necessary for defining the quantity of interest. *In medicine:* identical to dosage (see above). To avoid confusion in this document, the term dose has been reserved for use in the context described above and the term dosage has been used to indicate the medical context.
Emergency plan	A set of procedures to be implemented in the event of an accident.
Excess absolute risk (EAR)	The excess number of cases induced by one unit exposure, in addition to the spontaneous number of cases. ear is usually expressed as number of cases per year per 10 000 persons exposed to a dose of 1 Gy.
Exposure	The act or condition of being subject to irradiation. exposure can be either external exposure (irradiation by sources outside the body) or internal exposure (irradiation by sources inside the body). exposure can be classified as either normal exposure or potential exposure; either occupational, medical or public exposure; and, in intervention situations, either emergency exposure or chronic exposure. the term exposure is also used in radiation dosimetry to express the amount of ionization produced in air by ionizing radiation.
Formulation	The composition, both in terms of chemical form and quantity, for a pharmaceutical product (e.g. potassium iodide or iodate in

	milligrams and quantities of other ingredients of a tablet).
Generic intervention level (GIL)	A predetermined intervention level specified for a particular intervention. For example, the GIL for distribution of stable iodine recommended in the Basic Safety Standards is 100 mGy. GILs are primarily intended for planning purposes.
Graves' disease	A syndrome characterized by diffuse goitre, excessive functional activity of the thyroid gland (hyperthyroidism) and often associated with protrusion of the eyes (exophthalmos).
Hyperthyroidism	Excessive functional activity of the thyroid gland.
Hypocomplementaemic vasculitis	Hypocomplementaemic urticarial vasculitis syndrome (HUVS), a rare, severe, autoimmune disorder related to systemic lupus erythematosus. Symptoms caused by inflammation in blood vessels may be limited to the skin (recurrent urticaria) or involve multiple organs such as joints, kidneys, and lungs. The level of complements in the blood is depressed and complement antibodies are present. Severe allergic reaction to iodine has been described in these patients.
Hypothyroidism	Deficiency of thyroid activity.
Intervention	Any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of the accident.
Intervention level	The level of avertable dose at which a specific protective action or remedial action is taken in the event of emergency exposure or chronic exposure.

Ionizing radiation	For the purposes of radiation protection, radiation capable of producing ion pairs in biological material(s).
KI and KIO_3	Potassium iodide and potassium iodate, respectively, the two chemical forms of stable iodine recommended for protection against exposure to radioiodine.
Predistribution	Distribution to and supervised storage at local centres, such as police stations, hospitals, schools, fire stations, from where distribution to individuals can readily be made at short notice.
Reference level	Action level, intervention level, investigation level or recording level. Such levels may be established for any of the quantities determined in the practice of radiation protection.
Stable iodine	Non-radioactive isotope of iodine.
Stochastic effect	Radiation effects, generally occurring without a threshold level of dose, whose probability is proportional to the dose and whose severity is independent of the dose (see also deterministic effect).
T_4	Thyroxine, the hormone secreted by the thyroid gland.
Free T_4	The metabolically active form of thyroxine, circulating in the blood without being bound to a protein.
TSH	Thyroid-stimulating hormone, a hypophyseal hormone involved in regulating the thyroid function. An increased value indicates a latent or manifest deficiency in thyroid function. Used in screening of the newborn for congenital hypothyroidism.

Acronyms

FAO	Food and Agricultural Organization (a specialized United Nations agency)
IAEA	International Atomic Energy Agency (a specialized United Nations agency)
ILO	International Labour Organisation (a specialized United Nations agency)
NCRP	National Commission on Radiological Protection (a United States agency)
OECD/NEA	Organisation for Economic and Cultural Development/ Nuclear Energy Agency
PAHO	Pan American Health Organization (part of the Organization of American States)
WHO	World Health Organization (a specialized United Nations agency)