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Iodine Saturation of Thyroid Gland – Implementation of Iodine Saturation of Thyroid Gland in the event of Nuclear Accidents

Statement by the German Commission on Radiological Protection

Adopted at the 149th session of the Commission on Radiological Protection on 17 November, 1997

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Durchführung der Iodblockade der Schilddrüse bei kerntechnischen Unfällen

Stellungnahme der Strahlenschutzkommission

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In the event of any doubts about the meaning, the German original as published shall prevail.

Contents

1. Introduction

In its recommendation of 22/23 February 1996 **"Iodine Saturation of the Thyroid Gland in the event of Nuclear Accidents"** (Appendix), the Commission on Radiological Protection (SSK) adopted the World Health Organisation's internationally recognised recommendations of 1989. The principal innovations compared with the Basic Recommendations currently in force are the reductions in intervention reference levels, the changes in the iodine dose to be administered, and the restriction of iodine prophylaxis to persons aged up to 45 years.

Depending on the specific situation, the following procedure is recommended for implementing iodine prophylaxis in the Federal States.

2. Intervention reference levels

The Commission on Radiological Protection recommends the following intervention reference levels:

Group of persons	Thyroid dose
0 - 12 years and pregnant women	50 millisievert
13 - 45 years (including breast-feeding mothers)	250 millisievert
Adults over 45 years of age should not take iodine tablets, as in this group the health risk of serious thyroid disorders as a result of taking the tablets is greater than the radiation risk due to inhalation of radioactive iodine.	

3. Iodine dosage

The dosage scale for implementing iodine prophylaxis is as follows:

Group of persons	Daily dose in mg iodide	Daily dose in mg potassium iodide	Tablets of 130 mg potassium iodide
< 1 month	12.5	16.25	1/8
1 - 36 months	25	32.5	1/4
3 - 12 years	50	65	1/2
13 - 45 years	100	130	1
> 45 years	0	0	0
Iodine tablets are only to be taken when instructed by the competent authority. Pregnant women and breast-feeding mothers receive the same iodine dose as the 13 - 45 age group. As a rule it is sufficient to take iodine tablets once. In exceptional cases, however, the competent authority may recommend taking an additional tablet. For new-born children younger than one month the intake should however be confined to one day.			

4. Stocks of iodine tablets

The iodine tablets must be stored in such a way that rapid availability is guaranteed; distribution of the iodine tablets to the affected persons should as far as possible be completed before any inhalation.

Conclusions drawn from model calculations under Risk Study Phase B, and also logistical and general healthcare policy considerations call for the following preliminary distribution and/or stockpiling measures for iodine tablets:

Radius of 25 km around a nuclear power plant Stocks of iodine tablets for all persons up to age 45	
Radius 0 to 5 km	Advance distribution to households
Radius 5 to 10 km	Stocks of iodine tablets at several points in the communities (e.g. town hall, schools, hospitals, businesses) or advance distribution to households
Radius 10 to 25 km	Stocks in communities or in suitable establishments, advance distribution to households in exceptional cases only

Areas outside a radius of 25 km around a nuclear power plant in the entire territory of the Federal Republic of Germany

Central stocks (at several places, if appropriate) of iodine tablets for children up to age 12 and pregnant women

Where there has been no advance distribution of iodine tablets to households, distribution of the tablets within, if possible, 2 to 4 hours after a decision on their distribution should be ensured.

About 10 percent of the necessary iodine tablets should be kept available nation-wide as a reserve for removals or loss.

To enable all members of the public to take iodine tablets on a voluntary basis, prescription-free availability in pharmacies should be ensured.

Suitable stocks with appropriate logistics which make its possible if the need arises to supply iodine tablets to all children up to age 12 and pregnant women in risk areas (up to about 100 km from a facility) in good time – i.e. before any potential inhalation. As a rule it must be assumed that issuing of tablets within 12 hours after the decision on their distribution is ensured.

Where stockpiling of iodine tablets is necessary in connection with other nuclear facilities, it should be based on the specific hazard potential of the latter.

5. Packaging of tablets

(Here there is still a need for agreements with pharmaceutical manufacturers and with the Federal Pharmaceuticals Agency)

Packs:

– ”Standard Pack Potassium Iodide“: 10 tablets potassium iodide, 130 mg

– Large pack containing 20 to 50 individual packs of 10 tablets each.

A pack of 10 tablets is a sufficient supply for a 5-person household for the necessary duration of administration. Larger households receive the necessary additional quantity.

It must be easy to break the tablets into halves or quarters; this permits the necessary doses for the individual groups. It is recommended that they are taken with water. The dose for infants under 1 month old can be achieved by dissolving a $^1/_4$ tablet in water and administering half the solution.

The tablets must be in a normal market-type outer packaging with a clearly legible label, together with a suitable information sheet. In addition to the information required under pharmaceuticals legislation, this must also contain easily understood information about iodine prophylaxis and a warning about abuse and overdoses.

This pack information sheet replaces the existing Iodine Instruction Sheets A and B.

6. Costs

Regarding the question of costs, attention is drawn to the decision of Working Group V of the Federal States Interior Ministers Conference of 10/11 October 1996 on Agenda Item 12 No. 4, and the decision of the Federal States Committee on Nuclear Energy – Executive Committee – Agenda Item 6 of 5/6 December 1996.

7. Transitional arrangement

The measures proposed above serve to implement the new recommendations by the Commission on Radiological Protection. Until these measures are implemented, iodine prophylaxis may be based on the existing protective measures with the proviso that persons over 45 years of age do not receive any iodine tablets and that a single dose is normally sufficient for the other groups of persons.

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Appendix:
Iodine Saturation of Thyroid Gland in the event of Nuclear Accidents

Recommendation by the German Commission on Radiological Protection

Adopted at the 136th session of the Commission on Radiological Protection on 17 November, 1997; revised version with editorial amendments of 13 March 1997

1. Recommendations

The Commission on Radiological Protection (SSK) recommends the adoption of the recommendations of the World Health Organisation (WHO) of 1989 [1] on iodine prophylaxis for the thyroid gland. These essentially contain the following changes compared with the recommendations hitherto valid in the Federal Republic of Germany [2]:

– Reduction in the iodine dose administered, with only a single daily dose taken, and administration in accordance with the following dosage scale:

Age group	Daily dose (mg iodide)
< 1 month	12.5
1 - 36 months	25
3 - 12 years	50
13 - 45 years	100
> 45 years	0

Pregnant women and breast-feeding mothers receive the same iodine dose as juveniles and adults. The duration of administration should be confined to one day for new-born children and two days for pregnant women and breast-feeding mothers.

In Germany, which is an iodine-deficient area, metabolic disorders of the thyroid (functional autonomy) are relatively frequent with increasing age, and there is thus an increased risk of side effects of iodine prophylaxis. On the other hand, the risk of radiation-induced carcinoma of the thyroid falls off sharply with increasing age. For both these reasons, iodine prophylaxis is not recommended for persons over 45 years of age.

– Definition of the following thyroid dose commitments as intervention reference levels:

Age group	Organ dose
0 - 12 years, pregnant women	50 mSv
13 - 45 years	250 mSv

Iodine tablets should be kept available so that supplies can be provided for at least all children up to age 12 and pregnant women.

2. Rationale

2.1 Latest findings on release of iodine

In the light of the consequences of the Chernobyl reactor disaster there is a need to reconsider the recommendations on preventing uptake of radioactive iodine by the thyroid by taking iodine tablets.

In the event of a nuclear accident – as shown by the experience of Chernobyl – radioactive iodine may be carried through the air for hundreds of kilometres. Whereas the population can effectively protect themselves against ingestion of radioactive iodine with their food by refraining from consuming fresh vegetables and milk, it is much more difficult to avoid uptake of radioactive iodine via the air. Although staying indoors after a nuclear accident affords a certain protection, it may nevertheless become necessary to resort to additional protective measures (such as taking iodine tablets).

2.2 Effect of iodine prophylaxis

”Iodine prophylaxis“ (saturation of the thyroid) with doses of the order of 100 mg iodide and over brings about a reduction in the uptake of radioactive iodine by the thyroid by a factor of 90 or more, provided the tablets are taken in good time [3]. The iodine tablets should if possible be taken before the intake of radioactive iodine. Satisfactory prophylaxis can also be achieved if the intake of the radioactive iodine occurred less than 2 hours previously. Even several hours after the intake of radioactive iodine, the duration of its presence in the body is still reduced by taking iodine tablets. A first iodine tablet dose should however be taken not later than one day after intake of radioactive iodine, as otherwise excretion of the latter is delayed [4].

Radioactive iodine can have both stochastic and nonstochastic effects on the thyroid. Whereas it is not possible to lay down threshold doses for stochastic effects (formation of thyroid cancer), experience shows that nonstochastic effects (inflammation of the thyroid or hypothyroidism) hardly occur below organ doses of 10 Gy. In the event of a serious accident at a nuclear reactor, however, there is reason to expect that in the immediate vicinity incorporation of radioiodine with substantial radioactivity may take place, giving rise to thyroid doses of the order of several Gy.

2.3 Existing recommendations for the Federal Republic of Germany

The Federal Republic of Germany is among those countries that issued recommendations on iodine saturation of the thyroid in the context of nuclear emergencies at a very early stage – as early as 1975 (published 1977 in [5]). According to the ”Reference Levels for Staying Indoors, Taking Iodine Tablets and Evacuation“ [2], the lower reference level for taking iodine tablets is a dose of 200 mSv and the upper reference level a dose of 1 000 mSv. The upper and lower reference levels are higher than the WHO Recommendation [1] by a factor of 4. The reason given for this is that the greater part of the Federal Republic of Germany is an iodine-deficiency area and that taking iodine tablets involves an increased risk of undesirable side effects.

The present "Iodine Instruction Sheets" [2] lay down the following dosage scale (the figures are for tablets of 100 mg potassium iodide, corresponding to about 80 mg iodide):

– Adults, including pregnant women: initial dose 2 tablets of 100 mg potassium iodide each, then one tablet about every 8 hours up to a total of 10 tablets in a period of 3 to 4 days.

– Children (up to 40 kg body weight): initial dose 1 tablet, then $^1/_2$ tablet about every 8 hours up to a total of 5 tablets.

– Infants and babies (up to 20 kg body weight): $^1/_2$ tablet daily up to a total of 2 tablets.

2.4 WHO Recommendations of 1989

The WHO intervention levels [1] are – as outlined above – lower by a factor of 4 (lower intervention level 50 mSv, upper intervention level 250 mSv) than the corresponding intervention levels in the Federal Republic of Germany. The recommended dosages are also different (the WHO bases its dosage information on tablets with 100 mg iodide, which corresponds to 130 mg potassium iodide):

– Adults, pregnant women, breast-feeding mothers, and juveniles older than 12: 1 tablet per day.

– Children aged 3 to 12 years: $^1/_2$ tablet per day.

– Infants aged 1 month to 3 years: $^1/_4$ tablet per day.

– Neonates up to one month: $^1/_8$ tablet per day.

The WHO recommends restricting the total dose for pregnant women, breast-feeding mothers and neonates: neonates should receive only 1×12.5 mg iodide, pregnant women and breast-feeding mothers a maximum of 2×100 mg. This means that in the event of an accident with continuing release and intake, this risk group must be evacuated from the affected area with one to two days at the most.

2.5 Bringing the German recommendations into line with the international recommendations on iodine prophylaxis

There are various arguments in favour of bringing the German recommendations into line with the international recommendations. One is the fact that it is difficult for the public to understand if, for example, a nuclear accident takes place in a neighbouring country and the people there receive iodine tablets, while German people living possibly only a few kilometres away do not receive any because of the higher intervention levels. The most important argument in favour of changing the German interventions, however, is the result of experience following the Chernobyl reactor disaster: there was found to be a marked increase in the incidence of thyroid cancer in children even in areas of Belarus and the Ukraine that were several hundred kilometres distant. It was already known from the follow-up studies of survivors of the atomic bombs dropped on Hiroshima and Nagasaki that there was a sharp age-dependent rise in the additional relative risk of thyroid cancer development after radiation

exposure in children and juveniles, at 6.4 per Gy in 0 to 4-year-olds, 3.7 per Gy in 5 to 9-year-olds and 2.1 per Gy in 10 to 19-year-olds, whereas in older persons the increase in risk was only slight or non-existent at 0.7 per Gy in 20 to 29-year-olds, 0.9 per Gy in 30 to 39-year-olds and 0 per Gy in persons over 45 years of age [6]. It had not however been expected that appreciable incorporation of radioactive iodine with a consequent increase in the incidence of cancer in children might also take place far away from the scene of the accident [4].

It is in the light of this experience that the Commission on Radiological Protection recommends bringing the German intervention levels into line with the international recommendations and also planning appropriate organisational measures even at a considerable distance from nuclear reactors.

2.6 Setting an upper age limit for iodine prophylaxis for the thyroid

The Federal Republic of Germany is a low-iodine region. Recent studies indicate that a previously postulated north-south gradient with a marked deficiency in the south and adequate iodine levels in the north plays no more than a minor role. According to studies of schoolchildren during puberty, the incidence of goitre due to iodine-deficiency in this age group lies between 40 % and 60 % [7]. Whereas administration of high iodine doses of the order of 1 000 times the daily intake from food is relatively uncritical for younger persons, considerable complications may occur in older individuals with a long history of iodine-deficiency goitre. In long-standing cases of iodine-deficiency goitre frequently give rise to a disorder of the iodine metabolism of the thyroid known as ”functional autonomy“. Assuming that the frequency of iodine-deficiency goitre in members of the population over 40 to 50 years of age is about 20 to 30 %, and in the light of recent studies of the frequency of functional autonomy, it may be assumed that about 10 % of the population aged over 40 to 50 have such a disorder of the iodine metabolism of the thyroid [8]. In these individuals, iodine prophylaxis can give rise to serious cases of hyperthyroidism that are difficult to control. Since the associated risk must be rated higher than the slight, almost non-existent risk of a radiation-induced carcinoma of the thyroid, persons over about 45 years of age should be excluded from iodine prophylaxis [3].

This recommendation does however accept the risk that an accident-induced release may give rise to nonstochastic radiation damage in unprotected persons older than 45 who are in the immediate vicinity of nuclear reactors. These are relatively harmless disorders such as temporary inflammation of the thyroid gland or hypothyroidism that can easily be adjusted by medication. Moreover, since the group of persons potentially affected from the close vicinity of a nuclear reactor is considerably smaller than the older population living in remoter areas, it is recommended that iodine prophylaxis should as a general rule not be carried out for persons over the age of 45.

2.7 Literature

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