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NUCLEAR ENERGY AGENCY
COMMITTEE FOR RADIATION PROTECTION AND PUBLIC HEALTH

A COMPARISON OF METHODS OF ASSESSING AND MANAGING THE CARCINOGENIC RISKS ASSOCIATED WITH ASBESTOS, NICKEL (AND NICKEL COMPOUNDS) AND IONISING RADIATION

A Report of the Working Group on Risk Management

Report for the CRPPH
prepared by

Thierry Schneider, Samuel Lepicard
CEPN (Centre d’étude sur l’évaluation de la protection
dans le domaine nucléaire)

André Oudiz
IPSN (Institut de protection et de sûreté nucléaire)

Serge Gadbois, Gilles Hériard-Dubreuil
MUTADIS Consultants

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Pursuant to Article 1 of the Convention signed in Paris on 14th December 1960, and which came into force on 30th September 1961, the Organisation for Economic Co-operation and Development (OECD) shall promote policies designed:

- to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
- to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and
- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

The original Member countries of the OECD are Austria, Belgium, Canada, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The following countries became Members subsequently through accession at the dates indicated hereafter: Japan (28th April 1964), Finland (28th January 1969), Australia (7th June 1971), New Zealand (29th May 1973), Mexico (18th May 1994), the Czech Republic (21st December 1995), Hungary (7th May 1996), Poland (22nd November 1996) and the Republic of Korea (12th December 1996). The Commission of the European Communities takes part in the work of the OECD (Article 13 of the OECD Convention).

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of 27 OECD Member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

THE COMMITTEE ON RADIATION PROTECTION AND PUBLIC HEALTH (CRPPH)

The need to protect the public, workers and the environment from the deleterious effects of ionising radiation is the ultimate justification for a considerable fraction of the scientific, technical and regulatory efforts which are expended to address safety issues in the nuclear industry. One of the foundations of these efforts is a thorough understanding of radiation risks, including how these risks are assessed and managed, and including how these risks are addressed in a societal context. Radiation protection is a cross-cutting discipline that establishes programmes for the protection of the public and workers from the hazards of ionising radiation that then allows for the establishment of nuclear power, other peaceful uses of radiation and waste management operations to be safely conducted. The Committee on Radiation Protection and Public Health (CRPPH) has, within the NEA, the responsibility to study various aspects of these questions in the light of the following goals:

- to provide its Members with a high-level, visible forum for exchange and discussion;
- to seek common understanding of these issues;
- to advance the “state-of-the-art” in radiation protection theory and practice; and
- to promote international co-operative projects.

By addressing these goals, the CRPPH is helping to establish a safe work environment for nuclear power and waste management operations, as well as for medical and other industrial uses of ionising radiation. Performing this work in close collaboration with other international organisations, particularly the IAEA and the EC, assures that efforts are complimentary. Performing this work at the level of an internationally recognised committee of radiation protection experts, the CRPPH is also helping to promote international co-operation for more efficient and cost-effective discussion of these important radiation protection issues.

Since its inception in 1957, the CRPPH has filled for the NEA the essential role of assuring a high level of discussion and competence in the area of radiation protection. This has, in turn, contributed significantly to maintaining the appropriate equilibrium of concepts necessary for full-bodied and mature discussions in all domains of nuclear power.

The work of the CRPPH is divided into two broad areas; conceptual and policy issues, and operational radiation protection topics. By maintaining ongoing programmes in both these areas, the CRPPH has been able to satisfy the diverse needs of the Committee’s members, and has been able to maintain a balance between theory and practice and move theory to practice. This has also helped the Committee to produce results that are well founded and pragmatic. Although the membership of the CRPPH is largely regulatory, its various sub-groups also include experts from other governmental organisations as well as from private industry and academia. Representatives from other international organisations, most notably the IAEA and the European Commission, participate in many CRPPH activities to assure complementarity of efforts. This diversity of backgrounds and responsibilities has been essential to the success of the Committee’s approach to helping Member states’ radiation protection programmes establish and maintain safe nuclear power and waste management operation.

A COMPARISON OF METHODS OF ASSESSING AND MANAGING THE CARCINOGENIC RISKS ASSOCIATED WITH ASBESTOS, NICKEL (AND NICKEL COMPOUNDS) AND IONISING RADIATION (CRPPH WORKING GROUP ON RISK MANAGEMENT)

FOREWORD

The 1994 CRPPH collective opinion publication, "Radiation Protection Today and Tomorrow", noted the emerging effort to improve allocation of resources for protection through a more unified and broader approach to risk management, which henceforth will be referred to as Integrated Risk Management (IRM), and suggested that the field of radiation protection assume an active role in attaining improvements. The CRPPH, at its March 1996 meeting, decided to follow up on the comments in its 1994 collective opinion by establishing the Working Group on Integrated Risk Management (WGRM) to prepare a discussion paper which examines the broad issues associated with IRM.

The WGRM studied these issues, and presented a paper titled *Integrated Risk Management: An Emerging Concept for More Efficient Use of Risk Management Resources* [NEA/SAN/DOC(97)5] to the CRPPH during its 16 –17 April 1997 meeting. The paper provided a brief overview of emerging concepts for a more global approach to risk management and more efficient use of risk management resources. It also suggested how the radiation protection community might contribute to advancement of these concepts and what radiation protection has to gain. The paper stimulated a number of questions and comments on the part of CRPPH members. Fundamental questions about terminology were raised, and it was suggested that the use of the term “integrated” does not seem appropriate, in that it implies an aggregation of risk. Rather, the objective is to achieve a more coherent and consistent approach to the assessment and management of risks. It was suggested that the objective of this effort should be oriented toward identifying a more balanced and coherent approach to risk assessment and management, and to use case studies to illustrate the nature of the issues and what might be gained through such a coherent approach. Following this same logic, the word *Integrated* was eliminated from the name of the Working Group, which became the Working Group on Risk Management.

Based on these instructions from the CRPPH, three fundamentally different areas were identified where further studies might produce valuable information and insights. They are categorised as follows:

Category 1: Intercomparison of risk assessment and management approaches for different types of hazardous substances, such as radiation carcinogenic chemicals, or carcinogenic materials. An often noted perception expressed by radiation protection specialists is that a disproportionate amount of resources are allocated to reduction of radiation risks from nuclear practices when compared to allocations for health risks from non-nuclear activities. Whether these perceptions reflect a ubiquitous reality is certainly open to challenge. This area was identified in order to put this question into relative perspective, and to provide part of the philosophical basis necessary for making resource allocation decisions in areas that cut across risks.

Category 2: Intercomparison of the assessment and management of ionising radiation risk across practices, *e.g.* nuclear power, hospitals, industrial radiography. Again to somewhat in line with the above question of disproportionate efforts and resource allocation, this area was identified to investigate how radiation risks are dealt with in different industrial and regulatory contexts.

Category 3: Examination of risk transfer, interdisciplinary links and coherence in situations which require the application of the fundamental protection principles of more than one discipline in order to manage risk. Specifically, two areas in this category were identified: the first involves a comparison of nuclear safety issues and radiation safety issues, balancing nuclear safety and public potential exposure issues with worker exposures; the second involves a comparison of waste management and radiation protection issues, specifically to study approaches to the protection of present and future generations.

Based on these three categories, the WGRM began investigating case studies, however it was decided to focus on Category 1, which was seen as being of the broadest interest. The French Members of the WGRM were particularly interested in these comparative risk aspects, and performed a case study of the regulations and methodologies used in French for the assessment and management of three types of risk: asbestos, nickel aerosols, and ionising radiation. This work, performed jointly by the French radiation protection and nuclear safety institute (IPSN)[1] and the nuclear protection evaluation centre (CEPN)[3], was offered to the WGRM as one example of a national approach, in this case French, to the assessment and management of different types of risks.

At its meeting in April, 1999, the CRPPH reviewed a draft version of this report, agreeing that the French approach was interesting and useful, and should be published as a general distribution document by the CRPPH, representing work by one Member country.

The CRPPH would like to thank those who performed the work on this topic for the WGRM: Thierry Schneider[2], André Oudiz1, Samuel Lepicard[2], Serge Gadbois[3] and Gilles Heriard Dubreuil[3].

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1. IPSN (Institut de Protection et de Sûreté Nucléaire)
2. CEPN (Centre d’étude sur l’Evaluation de la Protection dans le domaine Nucléaire)
3. MUTADIS Consultants

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INTRODUCTION

Doubts have been expressed in recent years over the equity and social effectiveness of allocating resources to protection of the environment and health. A comparison of risk assessment and management practices in various industrial sectors is one way, among others, of addressing these concerns.

The comparison of risks is a long-standing practice, particularly with regard to the health and environmental risks associated with the different electricity production fuel cycles (coal, oil, nuclear, etc.). Moreover some radiological protection specialists are inclined to believe that the principles underlying the assessment and management of radiological risks are particularly sophisticated and could well be applied to many other types of risk.

Accordingly, in 1996 the Committee on Radiation Protection and Public Health of the OECD Nuclear Energy Agency set up a working group whose initial remit was to determine to what extent the methods for assessing radiological risk and the basic principles of the radiological protection might constitute a reference framework for "integrated risk management". The initial conclusions drawn by the working group prompted it to lower its initial aims in favour of what was undoubtedly a more modest project but one that, in many respects, was more realistic. Namely, it was to analyse, on the basis of practical examples, the consistency of the assessment and management of different carcinogenic risks and to draw attention, where necessary, to the problems that efforts to achieve such consistency posed.

The present study addresses the carcinogenic risks assessment and management of asbestos, nickel (and nickel compounds) and ionising radiation in France. To be more precise, we shall compare: asbestos and ionising radiation in the workplace; nickel (and nickel compounds) and ionising radiation in the environment.

The first part of the study sets out to determine whether the various stages in the risk assessment and management procedure (described below) are applicable, in terms of their basic principles, to the three case studies considered. In accordance with the procedure drawn up in 1983 by the US National Research Council [1], the risk assessment process is generally divided into three stages: hazard identification, determination of exposure-risk relationship, assessment of the number of people exposed and levels of exposure. There is also a decision-aiding stage based on the assessment of alternative prevention policies (risk management). Radiological protection provides the frame of reference for this latter stage. In 1977 the International Commission on Radiological Protection (ICRP) [2] drew up, and subsequently revised and enlarged [3], a decision-aiding framework designed to determine the dose levels that were "as low as reasonably achievable, economic and social factors being taken into account" (ALARA).

The second part of the study examines the main regulatory provisions in force in France with regard to the three sectors studied in order to identify the underlying principles and, in particular, the basis on which permissible exposure levels (PELs) are established (known as dose limits in the case of ionising radiation).

Besides regulatory provisions, we felt that it would also be useful in the third section to consider how the actors involved actually manage risks in practice. To this end we have analysed case studies of the implementation of protective measures in the various sectors examined and have also conducted a number of interviews with the actors concerned, particularly with regard to asbestos (managers in industry, officials responsible for risk prevention, competent administrations).

In this study, a quantitative comparison of risks in the various sectors is less important than a qualitative comparison of the risk-assessment and management approaches. The study therefore focuses on current practices and how they compare with each other. We feel that identifying similarities and differences is an objective in its own right in that it provides a basis on which to challenge, where necessary, some commonly-held beliefs regarding the advances that some sectors are assumed to have over others. The data we have collected reveal some significant similarities in the principles on which the assessment and management of risks of low-level exposure are based. At the same time, the procedures which are actually used in practice, despite being based on relatively distinct “instruments”[C1][4], ultimately produce results that are not dissimilar and that in general reflect the shared concern to devise “reasonable” solutions with regard to the prevention of carcinogenic risks.

It is also interesting to note the possibilities opened up by regional air quality plans as a result of the implementation of recent French legislation on air quality and the rational use of energyAlthough no prior conclusions may be drawn as to the manner in which these plans will shortly be put in place, it is possible that the preparation of these plans will offer the stakeholders an opportunity to place the social transactions needed to establish acceptable levels of risk within the regional socio-economic context.

Significant differences nonetheless remain between modes of management, notably with regard to the status of permissible exposure levels. The latter are a key reference in the case of asbestos and nickel but are of only secondary importance in the case of ionising radiation, where efforts are primarily focused on keeping exposure ALARA.

The descriptive analysis provided in the present study does not purport to serve as a basis for an explanatory framework that might shed light on the underlying reasons for the differences and similarities observed. The study was neither designed to analyse these underlying causes (which might give rise to complementary developments relating to several aspects such as the assessment and quantification of risks, the principles on which regulations in individual sectors are based, the administrative and financial resources devoted to protective actions, etc.), nor to provide precise details of the procedures governing transactions between the stakeholders looking for a compromise over the level of risk. This central aspect of the social construct of “acceptable risk” is a field of study in its own right. An analysis of the way in which actors perceive their role in their own particular context could, in particular, provide an opportunity to identify, with the help of these actors, the lessons they feel they could learn from gaining a deeper understanding of the practices of their peers in other contexts. This two-way exchange of experiences could yield operational benefits which in practical terms would meet the objectives of the initial project, namely to achieve greater consistency.

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[4] Optimisation for ionising radiation; good practices for asbestos; approach focused on the control of discharges for the nuclear installations; combined approach "installation based/environmentally -based" for nickel.

I. A PARTIALLY SHARED CONCEPTUAL APPROACH

I.A. Significant similarities

I.A.1 Proven carcinogenic effects on humans

Both epidemiological and animal studies have clearly and incontrovertibly demonstrated the carcinogenic properties of ionising radiation, asbestos fibres and certain nickel compounds at levels of exposure which show excess incidence of cancer.

The epidemiological studies carried out after the bombing of Hiroshima and Nagasaki in 1945 confirmed earlier observations of the higher than normal incidence of leukaemia among radiologists. As time went on, these studies started to reveal evidence that radiation could also cause other types of cancer such as cancer of the lung, digestive tracts, colon, breast, etc.

Rigorous epidemiological evidence of the excess incidence of lung cancer among workers exposed to asbestos was provided for the first time in 1950. First testimony of a link between exposure to asbestos and mesothelioma was established in 1960.

The excess incidence of lung and nose cancers attributable to high concentrations of mixed copper and nickel oxides as well as soluble nickel compounds emitted in nickel refinery was pointed out in the 1930s.

I.A.2 Existence of exposure-risk relationships

In all three cases, epidemiological studies demonstrated the link between relatively high levels of exposure and an excess incidence of cancer, in either absolute or relative models (exposure-risk relationships).

In the case of ionising radiation, the main basis for risk quantification was the "Life span study" which from 1950 onwards monitored the health record of 93000 survivors of the bombs dropped on Hiroshima and Nagasaki. The relationships deal with the incidence of leukaemia and "solid" tumours (lung, digestive system, colon, breast, etc.).

The model which linked cumulative exposure to asbestos to the increased risk of death from lung cancer was based on 11 cohort studies [4]. The relation between the concentration of airborne fibres and the increased incidence of death from mesothelioma is based on a multi-stage model of carcinogenesis in humans. This model, adjusted for 3 cohorts, provides an absolute estimate of the increased incidence of death from mesothelioma and not a relative estimate, as in the case of lung cancer [4].

In the case of nickel, ten epidemiological studies served as a basis for the risk quantification. Exposure risk relationship refers to lung cancer and exposure to nickel sulphides and nickel oxides present in nickel some nickel refinery [5]. This relationship is relatively straightforward and does not allow any distinction to be made between risks on the basis of age at exposure.

In the three cases, on the basis of models linking levels of exposure and the increased relative or absolute risk of cancer, statisticians have been able to use actuarial procedures commonly used in demographic studies to establish links between cumulative exposure[5] and the increased incidence of death from cancer over the whole lifetime of a population of individuals.

I.A.3 A shared assumption regarding the lack of threshold for low levels of exposure

In the case of all three agents, experts working in different sectors of activity considered that it is possible to make the cautious assumption that an increased incidence of cancer is associated with low levels of exposure. For the sake of risk-management, these experts adopted linear no-thresholds exposure-risk relationships obtained by extrapolating the results of epidemiological studies related to higher levels of exposure down to lower levels of exposure.

The increased lifetime risk of death from cancer is therefore considered to be proportional to the cumulative exposure over time. It should be noted that the slope of the relationship between individual exposure and lifetime increased risk of death from cancer expresses the average individual risk and undoubtedly corresponds only roughly to the risk of specific populations, whose increased risk could in principle be calculated more precisely (the very young or very elderly, male or female).

This limitation, which would be fundamental if the objective were to develop a model to forecast risk as part of a scientific theory of carcinogenesis, is only of minor importance in terms of risk management. In the latter case, the aim is to assess risk with a view to establishing suitable protective actions without attempting, for ethical reasons, to differentiate between groups of individuals likely to be exposed.

The excess individual lifetime risks of death from cancer by unit of exposure[6] are as follows:

	Excess Individual Lifetime Risk of Death from Cancer
Ionising Radiation: Workers	4×10^{-5} per mSv
Ionising Radiation: General Public	5×10^{-5} per mSv
Asbestos: Workers	4×10^{-4} per year-[f/ml]
Nickel: General Public	1.4×10^{-9} per year-[ng/m^3]

I.A.4 Existence of indicators of cumulative exposure over time

In all three cases, cumulative individual exposure over time is an indicator of the increased lifetime risk of death from cancer. There is, however, a limitation with regard to sporadic exposure to asbestos (see I-B).

Because a no threshold linear relationship has been assumed between cumulative exposure and the excess lifetime risk of death from cancer, it is possible to devise indicators for collective exposure. These indicators are the man-sievert for ionising radiation, man-year-[f/ml] for asbestos and man-year-[ng/m^3] for nickel.

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[5] Expressed in sievert for IR, in year.[fibre/ml] for asbestos, in year.[ng.m-3] for nickel.

[6] We refer to the exposure unit currently in use in each case.

I.A.5 Approximations of the same order for the limits of validity of the indicator for cumulative exposure

It should be noted that the cumulative exposure indicator may conceal significant discrepancies with regard to assessment of the risk (of the order of 20-30%), depending on the type of exposure and the person exposed (notably in the case of mesothelioma resulting from exposure to asbestos or solid cancers in the case of exposure to ionising radiation).

I.A.6 Predictive assessment of protective actions and choice of actions

In all three cases it is possible to use cumulative exposure to assess the predictive effectiveness of protective actions, subject to the limitation on sporadic exposure with regard to asbestos.

Cumulative exposure is itself based on knowledge of the level and total duration of exposure. It is therefore possible to deduce from these two parameters the health risk that has been avoided, even if such an estimate involves substantial simplification (I-A-5). This approach should make it possible (at least at the conceptual level) to inform the choice of protective action in each sector (ionising radiation, asbestos and nickel). It should then be possible to compare the cost of protective actions with the expected benefit in terms of reduced exposure, provided that monetary values are calculated for the man-sievert, man-year-[f/ml] and man-year-[ng/m^3].

I.B. Significant differences

I.B.1 Scope of validity of the exposure-risk relationship for asbestos and nickel

The exposure-risk relationship in the case of lung cancer and mesothelioma does not apply to discontinuous occupational exposures with high concentration levels during short periods (so-called sporadic exposures). In such cases not enough reliable data are available to reconstruct the doses actually inhaled by workers. While data regarding concentrations may be available, data on effective exposure times are not. The exposure-risk relationship may for example be supra-linear if a low average dose administered in sporadic exposure peaks was associated with a higher risk than an identical average dose administered evenly over time [4].

In the case of nickel, while for specific nickel compounds no excess of cancer risk has been observed for occupational exposures, the lack of a precise chemical characterisation of the nickel compounds present in the environment leads to an assessment in terms of total nickel concentration. This results in over-estimation of the associated risks.

II. SIGNIFICANTLY DIFFERENT REGULATORY APPROACHES

II.A Different general principles

One of the key principles enshrined in the radiological protection system is the aim to keep doses as low as reasonably achievable, economic and social factors being taken into account (ALARA). In reality, individual dose limits would seem to be a "safety net" designed to protect individuals against exposure to a risk that might be deemed to be excessive. The main objective is therefore not to comply with dose limits, but to keep exposures ALARA [3].

With regard to asbestos and nickel, the permissible exposure limits (PEL) are set at values which reflect the aim of reducing the residual carcinogenic risk[7] to a very low level. In the case of nickel, for example, the future daughter directive of directive 96/62/EC of September 1996 specifies a dose limit for environmental nickel amounting to a few tens of ng/m^3. For asbestos, the requirement for compliance with a PEL of 0.1 f/ml per hour in the working environment is accompanied by a general clause, valid for all occupational carcinogens, stipulating that exposure must be reduced as low as technically feasible.

In practice, with regard to both nickel in the environment and asbestos in the workplace, achieving the PEL is the first, and often very ambitious, objective. The exposure levels at the time these PELs are adopted are usually at a much higher level and the initial aim is therefore to reduce exposure levels to the PEL and then to ensure that they are not subsequently exceeded.

There is a similarity in all three cases, however, in that the PEL is not considered to be a threshold and it is accepted, as a precautionary measure, that below the PEL there still remains a residual carcinogenic risk.

II.B Different basis for the PEL

The dose or exposure limits for ionising radiation (IR) and nickel are based on dose-risk or exposure-risk relationships. The risk level associated with dose limits in the case of ionising radiation is set by the International Commission on Radiological Protection on the basis of relatively non-explicit considerations and notably comparison with the risk of death in other reputedly "safe" industrial sectors, with regard to occupational exposures, and comparison with the doses arising from natural background radiation in the case of members of the general public. No PEL for nickel in the environment has been established to date. The level eventually set will be based on the work of the World Health Organisation, which refers to an individual excess lifetime risk of death from cancer of 10^{-5}, although it does not correspond to a formal recommendation.

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[7] Rigorously, the expression excess risk should be used: i.e. the risk associated with exposure to the considered pollutant added to the "background" risk.

In the case of asbestos, the PEL in France is not based on the exposure-risk relationship but on concerns of a different nature:

(1) According to one of the epidemiological studies available, the value of 0.1 f/ml is the lowest concentration that, over a period of 50 years, produces a statistically significant[8] increased risk.

2) It would also appear that 0.1 f/ml is in practice the limit for the sensitivity of the measuring instruments used in industry.

The PELs are set out in the table below.

In view of the differences in terms of general principles and technical bases, there is no reason why the risk levels associated with these PELs should be uniform and therefore no attempt has been made to compare them. It needs to be borne in mind, however, that compliance with the limit value is not a sufficient objective with regard to ionising radiation. The emphasis here is placed on the ALARA principle, which in most situations, and for most of the persons exposed, is significantly lower than the dose limit. In the case of nickel and asbestos, by contrast, the PEL is seen more as a target to be aimed at. In addition, it is also worth taking into consideration, with a view to comparing risks, all exposure pathways and any cumulative exposures to different chemical carcinogens.

	PEL
IR: Workers	100 mSv over 5 consecutive years, annual dose less than 50 mSv
Asbestos: Workers	0.1 f/ml, average over 1 hour
IR: General Public	1 mSv/year
Nickel: General Public	10 to several tens of ng/m^3

II.C A specific approach to the management of releases to the environment

A two-fold approach is adopted in the case of both nickel and IR: firstly, an approach by installation; and secondly an environmentally-based approach.

II.C.1 Similar approaches by installations

In the case of nuclear installations, the authorities grant discharge permits on the basis of an analysis of the technologies used by the operators, which are compared with the best available technologies at an economically acceptable cost. The authorities also take account of the characteristics of the environment, the transfer of radionuclides to the environment as well as the characteristics of the population concerned.

Similarly, in the case of nickel, the limit values for discharge for each installation are determined through reference to the best available technology after taking account of the technical characteristics of the installation, its geographical situation and the local environment.

In both cases, although the aim is to safeguard health and the environment, no direct reference is made to a given level of risk or concentration that is to be achieved.

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[8] 0.1 f/ml over the 50 year period: i.e. 5 year[f/ml].

II.C.2 Different environmentally-based approaches

In addition to an approach based on review of the best available technologies (BAT), an objective in terms of a PEL for concentration in the ambient air has been specified for nickel. This PEL must be complied with at either the local or the regional level in the knowledge that there are various sources of nickel discharges. In view of the inherent difficulties in modelling nickel releases to the environment, it is only empirically (by monitoring air samples) that it can be determined whether the adoption of the BAT at the level of installations will ensure compliance with ambient air PEL in a given region. In this case, the environmental approach entails a second regulatory framework (set up under French clean air legislation or the EU directive on Air Quality – Air Management). This framework establishes, in principle, a local negotiating forum designed to share efforts to reduce pollution between the various actors responsible for emissions, the aim being to comply with the PEL. It is therefore at this stage that an assessment is made of expected health and environmental impacts in order to determine, in the first phase of in the process, the local priorities in terms of protection. These priorities will then be validated, where necessary, in a second phase through the implementation of an epidemiological programme to monitor the populations exposed.

The initial choice of a policy towards protection against the risks posed by nickel is therefore based on measurement of the level of exposure of populations and comparison of this level with the PEL.

In the case of discharges from nuclear installations, the environmental approach cannot be dissociated from the approach by installation. In particular, the regulations provide for an assessment of transfers of radionuclides to populations through a variety of pathways atmospheric dispersal, deposition in the soil, agricultural production. The doses resulting from external exposure and the activities absorbed through internal exposure must meet a limiting condition[9] relating to the cumulative value of such exposures.

A number of restrictions are imposed on the operator with regard to environmental impacts. These restrictions concern measurable parameters (e.g. radioactivity in discharge systems, effluent flow rates through such systems, level of radioactivity added to the environment) and not the doses received by the populations. The aim is to verify that discharges meet the requirements set out in the regulatory permit with regard to the quantities released and the mode of release of contaminants. A higher than authorised level would constitute a breach of the regulations. The aim of such environmental monitoring is not to assess the dosimetric impact of discharges on the populations exposed.

For most of the installations in the nuclear fuel cycle[10], the approach by installation (in order to achieve discharge levels that are "as low as reasonably achievable") entails specifying maximum authorised discharge levels.

II.D Significant differences regarding technical specifications

In the case of nickel and IR, the regulations make no provision with regard to the technical means of reducing discharges. In contrast, in the case of (friable) asbestos removal and treatment sites, the technical requirements are laid down in the regulations and leave little room for manoeuvre.

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[9] The latter combines the external dose limit and the annual limit of intake associated to each radionuclide.

[10] For installations such as mill tailing storages or the surface waste disposal, the environmentally-based approach may constrain the quantities released into the environment.

III. RISK ASSESSMENT AND MANAGEMENT PRACTICES FITTED FOR EACH CARCINOGENIC AGENT

III.A Occupational carcinogenic risks

III.A.1 Asbestos treatment sites (sector 2, friable)

Further to the ban on the production and processing of asbestos, friable asbestos treatment sites (sector 2) constitute the sector of activity where, in view of the high potential risks involved, the most professional approach has been adopted to management of the asbestos risk. This management consists actually in transferring the risk away from the public to a population of workers maintained under medical surveillance.

Despite the gradual introduction of professional practices into this sector of activity, asbestos treatment poses a number of problems with regard to risk management.

III.A.1.a Predictive risk-assessment on work sites

Risk assessment, as one of the general principles of occupational risk prevention and of the specific rules with regard to carcinogenic risk, is the first means of averting the risks associated with asbestos. It is aimed in particular at determining the duration and level of exposure of workers to asbestos fibres.

The inherent risks in buildings that need to be treated depend upon a number of factors including the type and condition of structures containing asbestos[11], the volume and layout of areas where work is to be carried out, as well as the type of work to be performed on the structures[12]. The risks lie not only in the asbestos material but also in the way in which it is treated, the environment in which it is treated and in the interaction between these different factors. The assessment of future risks is therefore a complex task that cannot be reduced to simply measuring emissions at source.

A measurement is nonetheless made of airborne dust levels before installing the containment system needed to carry out the asbestos treatment work. This measurement is primarily aimed at determining the “zero point”, i.e. the level before work commences which can subsequently be compared with the level once the asbestos has been treated. It is therefore aimed at determining the exposure level for the populations that will use the building once work has been completed. This measurement is also used to assess the risk run by the workers in charge of preparing the work site (installation of a collective protection system in the form of a containment enclosure). It does not take account, however, of the possible release into the air of loose fibres in the course of the earlier site preparation work.

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[11] These structures concern not only flocking, insulation and ceilings which inventory is mandatory but also other potential sources such as floor-covering.

[12] Asbestos may be considered as an "interactive" source: fibres emissions rates vary strongly depending whether cutting operations are performed manually or with electrical devices.

The measurements available on site before work commences therefore only provide partial data regarding risks. It is generally through an overall qualitative assessment, based on knowledge of work procedures[13] and on experience with earlier treatment operations, that the risks are assessed. Admittedly asbestos presents a risk, but there are also other risks associated with work sites in buildings such as the danger of a fall, electrocution, etc. The assessment of future risks is therefore also aimed at placing the asbestos risk within the general framework of risk prevention in the building and public works sector (industrial accidents in particular).

III.A.1.b Preparation of the protection strategy

The choice of protection system is the outcome of the drafting of a "removal plan" by the firm responsible for the work site, in which the firm lists the resources (technical and human) deployed on the work site and the procedures relating to the work (specifications of protection systems and prevention procedures). This document is sent for opinion to the prevention experts[14] to allow them to assess the coherence and comprehensiveness of the protection systems put in place.

In particular, besides a predictive risk-assessment, French regulations require a containment system to be installed at the work site with a 3 or 5-compartment air-lock as well as the use of supplied-air personal protective equipment (PPE) that is virtually air-tight.

Nonetheless when supplied-air PPE presents risks of accidental exposure (due to a tear in the fabric, loss of face mask fit) or other risks (falls), the firm and the prevention authorities may discuss the advisability of using a PPE with a TMP3 face mask with filter and air supply which offers less protection but gives workers greater freedom of movement. Similarly, the risk of electrocution may prompt the prevention authorities and the firm to decide against using sprayed liquids to capture airborne fibres and thus reduce the level of airborne dust in the ambient air.

The dust levels expected during the treatment operation is one of the factors taken into account by the prevention experts. These experts can make use of databases currently being developed[15] to determine the limits to the protection factor afforded by the filtering mask and are cognisant of the fact that the level of airborne dust in the filtered air supply must be less than the PEL. As it is very difficult to assess future risks when discussing the removal plan, the on-site visit made by the prevention authorities is a key element which enables them to ensure that the protection systems put in place are adequate. This inspection visit, which because of the large number of work sites to be visited and the number of inspectors available is not always carried out in practice, is made either when the asbestos removal work begins or once work is already in progress. Ultimately the decision as to when the inspection is made is not based on a comparative cost-benefit analysis of the existing risks and remedies available.

III.A.1.c Assessment of exposure levels while work is in progress

The sole measurement required under the regulations is that of dust levels in the compartment in the entrance and exit airlocks where workers collect their respirators. The exposure while work is in progress cannot be accurately measured. It is difficult to measure the number of asbestos fibres in the air

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[13] And related dust levels, notably thanks to the INRS studies [7].

[14] Authorities, advising organisations and corporate prevention responsibles.

[15] Notably Evalutil, as well as studies carried out by INRS in view of assessing personal protective equipment efficiency.

inhaled through face-masks and measurements need to be made frequently in order to ensure that the results are representative. Indicative values are established on the basis of the dust level of the ambient air multiplied by the safety rating of the PPE. Several uncertainties affect the accuracy of these estimates.

The PPE safety ratings provided by the manufacturers are nominal values established under conditions that are not particularly representative of the reality of working conditions and overestimate the real degree of protection afforded by thePPEs. Moreover, the concentration of asbestos fibres at a work site can vary substantially from one work area to another and also in accordance with the degree of negative pressure (which itself can vary over the course of the working day on site). In addition, the efficiency of PPEs is not invariable and may be adversely affected by the position in which the worker finds himself and also by incidents (poor mask fit, power cuts, etc.).

Consequently measurement subsequent to exposure is not a central factor in the control of occupational exposure to asbestos[16]. The development of a continuous dust level monitoring system, to be worn by workers, similar to that used in asbestos mines, should help to improve these estimates. In any case the latter will always remain no more than very approximately measurements of a cumulative dose over a certain period of time and will not make it possible to satisfactorily verify the application of an PEL (0.1 f/ml over a period of one hour).

Under current work site practices, exposure levels are estimated on the basis of secondary indicators such as work area entrance and exit logs (length of exposure time) and work procedures (associated concentrations).

III.A.1.d Controlling risk in the course of work operations

Because of the difficulties involved in measuring occupational exposure, riskcontrol will primarily focus of the protection system put in place. Thus the prevention experts will focus their attention on the factors influencing the collective and individual protection levels laid down in the removal plan, notably [7]:

- work management,
- electric installations,
- detailed characteristics of each room,
- characteristics of the containment,
- characteristics of the airlock,
- atmosphere monitoring,
- means for respiratory protection,
- masks,
- tools,
- operating processes (wet or dry,…),

III.A.1.e Vectors of progress and unwanted effects

Improvement of knowledge

Despite the difficulty of assessing the efficiency of a given protection system on a work site, this does not mean to say that no attempt is made to determine the effectiveness of protection systems with regard to exposures and the PEL. While admittedly relatively few efforts are made by firms to address this

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[16] On the other hands, some measurements are performed in the work site periphery in view of making sure that asbestos pollution remains confined inside the work site.

issue directly on their work sites, some interesting work has been conducted in this area by national prevention experts. Several initiatives have recently been launched with a view to gaining a better knowledge of asbestos exposure and the efficiency of protection systems according to the type of job, the operations carried out and the type of PPE. As well as meeting their concern to develop a reliable protection system for use on work sites, the prevention experts are thereby also attempting to determine the efficiency of different protection systems with regard to exposure. The INRS, for example, is carrying out a study of asbestos exposure at various work sites by focusing on the different types of respirator and protective clothing available. The parameters addressed by the INRS investigators are the levels of airborne asbestos dust and the levels present in the air inside workers' face-masks. Similarly, the Evalutil database, developed by a team of researchers in a joint initiative by the Ministry of Labour and the CNAMTS, currently contains data relating to over 2000 jobs embracing approximately 700 professions and 160 sectors of activity.

Learning and responsibility

Knowledge about the efficiency of resources and technical know-how are both evolving and the various actors in the sector (firms, prevention experts) are involved in a learning process. The knowledge and technical resources needed to comply with the provisions of regulatory text with regard to the different types of situation that can arise on the work site have not yet been completely drawn up. In view of this situation, while nonetheless learning, firms feel the need to have compliance confirmed and they tend to seek for a final and permanent work site authorisation from the prevention authorities, which are also advisers. In contrast, the prevention authorities, who are themselves involved in a learning process, help firms by pointing out mistakes, but do not want to define the necessary protection measures. In their eyes, firms must assume their responsibilities with regard to prevention, which is part of the learning process and encourages firms to make progress. Moreover, excessive involvement on the part of the prevention authorities in the choice of protection systems would cast them in the double role of ***judge and jury.***

The removal plan is central to the relationship between the firm and the prevention experts. First conceived as a purely administrative document, this plan would seem to be evolving into an increasingly detailed presentation of protection systems, on the basis of which the firm can receive comments of a practical nature from the prevention experts. This development reflects the common interest firms and prevention experts have in putting in place an appropriate and satisfactory system upstream of the work site stage in order to reduce cost over-runs resulting from late changes or even interruptions in operations on the work site.

Risk culture and degree of discomfort

Workers have an important role to play in prevention. Not directly involved in the technical aspects, they represent the second challenge in the relationship between the various actors in the asbestos risk management process. Under the regulations, firms must make substantial efforts to train and raise the awareness of workers involved in asbestos removal. In practice, a high awareness of risk tends to increase in the context of the preparation of removal plan and the implementation of the asbestos regulation. Furthermore, a global improvement of the professionalism in the asbestos removal sector is observed. Nevertheless, the involvement of workers and the vigilance shown by the latter, which underpin the efficiency of risk management, may be completely negated by the high degree of discomfort associated with activities. The attention paid by workers to the protection system (wearing of face-masks) and protection procedures (passage through the 5 compartments in the air-lock) can sometimes be eroded by painful physical labour and frequent entries into the area (4 times a day). Under the regulations it is the responsibility of the occupational medicine to ensure that uncomfortable working conditions are taken into account to ensure that the protection system remains reliable. Occupational medicine has taken relatively little interest in this area. Some prevention experts are stepping up their efforts to ensure that this aspect is taken into account by firms.

Economic dimension

Safety can account for up to 80 % of the cost of a work site [6]. While the call for tender procedure would clearly seem to favour the cheapest bidder, the parties issuing calls for tender have a responsibility to ensure that the work site is managed efficiently and their ultimate aim is to ensure that the surfaces treated comply with the regulations concerning the protection of populations exposed to a risk arising from asbestos in buildings. Some of them prone to take account of the fact that the cost reflects the level of quality provided by the firms. Indeed since 1994 a shared body of knowledge has gradually built up between actors with regard to the economic aspect of safety on asbestos removal work sites, which is helping to establish rules of practice regarding replies to calls for tender [7].

Acceptability of risks

Asbestos risk control also takes account of the existence of other risks inherent in the building and public works sector (falls, accidents). The decision to opt for a lower level of personal protection against asbestos exposure in order to counter other risks can occasionally arise on a work site. It is difficult to base such a decision on objective comparisons (such as cost-benefit analysis). It is nonetheless the responsibility of the firm and the prevention experts to determine in situ the relevance of one or the other option on the basis of a qualitative assessment of the various risks and in particular on the experience feedback.

III.A.2 Ionising radiation: external exposure in nuclear power plants

In view of the scale of the nuclear power plant programme in France, the experience which operators have gained with the management of occupational radiological risks in nuclear power plants has gradually prompted them to develop a structured ALARA approach. Workplaces in nuclear installations are properly defined and exposures are basically linked to external irradiation, thus allowing the operator to calculate expected dose rates for a given workplace and allowing predictive risk-assessment to be made.

The operator (EdF) and some of its sub-contractors have therefore developed ALARA programmes that consist of:

- Setting dosimetric objectives at the end of the work preparation phase (individual and collective exposures);

- Putting in place an information logging system to allow exposures to be monitored over the course of the programme of work; to this end, an operational dosimetric system is systematically put in place by the operator himself, in addition to the regulatory dosimetric system, so that he can regularly monitor the exposures of both his own employees and the employees of sub-contractors working in his installation;

- Analysis of results (dose rates at the workplace, working time spent under exposure, individual doses by task) in order to establish feedback that can be used to forecast and optimise exposures for subsequent work.

The implementation of these programmes has led the operator to put in place specific structures which facilitate the account taken of radiological risk in the general organisation of work, such as ALARA Committees, run by a high-level supervisor, or ALARA groups made up of representatives of various job specialities and levels of management within the organisation of both the operator and sub-contractors.

III.A.2.a Predictive risk-assessment

Many tools have been developed in order to assess exposure levels: measuring systems or dose rates modelling, software permitting analytical forecasts of the dose rates per task, per work organisation modes and procedures, experience feedback databases.

This approach has in fact been made possible by the standardisation of installations and the fact that specific jobs are defined beforehand. These assessments are also made when installations are still in the design stage or when major maintenance programmes, such as that for the replacement of steam generators, are being drawn up.

It should be noted that the approach adopted by operators is based on assessment of individual dose rates and the distribution of individual doses, the number of employees exposed and the collective dose. The analysis makes no direct reference to the radiation induced health risk, but instead is based on the collective dose. This dose, as we have seen in Part I, is an indicator that takes account of the average risk in a group of individuals assumed to exhibit average biological and demographic characteristics. In other words, the forecast analysis does not set out to integrate the characteristics of the population exposed, namely age, exposure profile and any prior sensitivity to radiation.

III.A.2.b Choice of protection system

Once exposure levels have been assessed, the range of possible protective actions must be reviewed in order to select those which are consistent with the available resources and which ensure that the risks are distributed in what is felt to be an even-handed manner between individuals. The use of economic analysis (through cost-benefit analysis) for this purpose was introduced in the early 1970s by the ICRP [2]. The ICRP proposed that investment in protection should be chosen on the basis of an “optimum model” which would balance expenditure on protection against the health benefits (expressed in monetary terms) expected to be gained from such investment. At the international level, some operators of nuclear installations have gradually started to put in place a system of monetary values for man-sievert corresponding to the amount that they are willing to spend in order to reduce exposures. In France, it was in the early 1990s that the central departments of EdF adopted a system of monetary values originally used to facilitate the choice of protection system for major projects (such as replacement of a steam generator). Since then, this system has been used for other major projects but its use is by no means widespread at the level of nuclear plant operation.

A recent survey of practices at the international level shows that the concept of assigning a monetary value to the man-sievert is increasingly widespread among operators and regulatory authorities, although its use is recommended and not compulsory. In 1997, although 75% of operators had a system of monetary values for man-sievert in place, the formal use of this system has not yet entered into everyday practice. The monetary value is primarily used to inform important decisions (modification of installations, costly repairs, etc.). It is primarily seen by users as a tool which reduces the subjectivity of choices and which is occasionally used in discussions with sub-contractors or authorities.

III.A.2.c Assessment of exposure levels while work is in progress

The first system put in place consisted in monitoring exposure levels through a system of operational dosimetry. This system allowed the operator to programme remedial actions, where necessary, while maintenance operations were being carried out. In addition, the system allowed comparisons to be made of the dosimetric results from nuclear reactors both in France and abroad. The results of this comparative approach were a major factor in the decision by EdF, in the early 1990s, to adopt the ALARA approach, based on a policy applicable to all French nuclear power plants. In this specific case, it was primarily the results in terms of the collective dose which prompted this decision. It is also worth noting the development at the international level, under the aegis of the NEA, of an international database on collective doses for nuclear reactors, thus encouraging, firstly, comparisons in terms of dosimetry and, secondly, the pooling of experience with regard to the dosimetric aspects of the main maintenance operations.

III.A.2.d Controlling risk in the course of work operations

The first level of risk control consists in verification of compliance with annual individual exposure limits. In France, the agency responsible for verifying such compliance is the Office de Protection contre les Rayonnements Ionisants. However, as we saw in section II, French regulations currently in force have already adopted the ALARA principle. It should be noted that from a legal standpoint the ALARA process corresponds to an obligation in terms of behaviour[17] and not in terms of results, as it is in the case of compliance with exposure limits. Objectives can therefore only be set on a case-by-case basis since they will depend upon the type of operation contemplated, the expected radiological conditions, the work process employed and the protection efforts deemed to be reasonable.

In practice, the files forwarded by operators in connection with licensing or decommissioning requests or for the performance of major maintenance operations with respect to nuclear installations include a section relating to the ALARA approach. The regulatory agency (currently the DSIN), with the technical support of the IPSN, analyses the actions proposed by the operator to keep occupational exposures as low as reasonably achievable. This analysis is providing more and more a basis for a dialogue between the operator, the agency and its technical support services regarding the ALARA approach. However, it should be noted that there is ongoing debate over the assessment criteria used in this area, which are still under development. In particular, the concept of dose constraint and, more generally, radiation protection objectives are focussing particular attention. Besides which, the French regulatory agency does not feel that reference to a system of monetary values for man-sievert is timely.

The process of post-evaluation of the implementation of the ALARA process sets out to analyse the discrepancies between exposure objectives and results by taking account of actual working conditions compared with those predicted. The dialogue that is gradually starting to develop between operators (involving several different levels of management) and the regulatory agency and its technical support services is tending to reinforce this assessment work.

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[17] This obligation in terms of behaviour is called in juridical terms as an obligation as to means. Therefore, the ALARA approach is analogous to the obligation to act and manage affairs as a "bonus paterfamilias".

III.A.2.e Vectors of progress and unwanted effects

A monetary value as the basis of a transaction between actors

One of the widely debated elements in the implementation of an ALARA approach is the role played by economic analysis and setting up a monetary value for the man-sievert. However, if the latter is to play an appropriate role in the attempt to obtain a level of exposure as low as reasonably achievable, this value must be the object of a "social transaction" between the actors [8]. Apart from the fact that this value cannot validly be laid down "by law", the purpose of this transaction is to put in place an aid to decision making acceptable to all parties in order to meet shared objectives. At present, however, such an approach remains limited in that the monetary values for man-sievert are not generally applied in installations and in that, in the cases where they are used, the employees (or their representatives) concerned are not involved in the choice of values.

Dissemination of a common culture of low exposure risks

The "ALARA culture" might be defined as consisting in *shared knowledge, common objectives, attitudes and behavioural approaches that allow the management of occupational exposures to benefit from the informed assumption of responsibilities by the various actors concerned* [9]. The shared knowledge is therefore primarily the bases for the precautionary principle and responsibility with regard to the effects associated with low exposure levels to ionising radiation. Such a culture is not as yet fully in place and still requires training programmes to be regularly administered at different levels within management. As for the definition of common objectives, the aim here is for the enterprise to adopt dosimetric objectives that will translate into practice the strategy adopted towards management of the radiological risk. The objectives adopted by EdF in 1996, for example, were as follows:

- A collective dose in all French nuclear power plants in the year 2000 of 1.2 man-Sv/year/unit, combined with a objective with regard to the distribution of individual doses of eliminating doses higher than 20 mSv/year;
- Annual collective dose objectives per site according to the volume and type of work to be carried out (objectives specified in site management contracts with the General Management of EdF);
- Objectives per maintenance operation.

Concerted introduction of assessment criteria

At present there is only limited experience feedback from the regulatory agency regarding the assessment of the ALARA process implemented by the operator. However, there is a need for the parties to work together to develop assessment criteria and to create an area for dialogue that will allow operators, the regulatory agency and its technical support partners to discuss the conditions for implementation of the ALARA approach.

III.A.3 Ionising radiation: internal exposure in fuel fabrication installations

Among the exposure pathways to ionising radiation in the workplace, inhalation poses a complex problem in terms of the assessment and measurement of exposures. From this standpoint, the situation is similar to that of exposure to asbestos in the workplace. We shall therefore consider here internal exposures arising from the inhalation of radioactive compounds of the type found in installations involved in fuel fabrication.

III.A.3.a Predictive risk-assessment

Assessment of concentrations

In order to model exposure levels, it is first necessary to assess the concentrations present in the ambient air in workshops during the working day. Depending upon the specific job of work considered, however, the concentration will to a large extent depend on the type of operation carried out in these workshops (or even on the procedures followed by those who carry them out), resulting in concentration peaks that it is impossible to simply assess through predictive models. This situation differs from those generally encountered in the assessment of future levels of external exposure to ionising radiation where the dose rate is relatively easy to take into account when modelling the exposure. As a result, only the use of a programme to measure concentrations in the ambient air in workshops and at workplaces will be able to provide the information needed to assess the risk.

Assessment of internal doses

Furthermore, once the concentration has been estimated, the predictive assessment of internal doses arising from inhalation requires the use of a series of models:

- The internal exposure model, relating specifically to the measurement method utilised, allows initial determination of the inhaled activity (in Bq) on the basis of the measured parameter (in Bq/l or Bq/m3) and all the characteristics of the exposure (spatial and temporal profile of exposure, which will depend upon the characteristics of the environment) and the characteristics of the average exposed individual (respiratory flow rate);
- The dosimetric model allows correlation of the activity inhaled to the committed effective dose, in most cases simply by applying dose factors according to the nature of compounds (in Sv/Bq).

It should be noted that the degree to which the predictive doses reflect the actual conditions is closely linked to the accuracy of the exposure model. However, the degree to which these estimates are realistic also depends upon the accuracy of the various sub-models (pulmonary, digestive tract, biokinetics and irradiation) of the dosimetric model for inhalation. One essential point that needs to be taken into consideration is the high sensitivity of the pulmonary sub-model to the solubility and ***granulometry*** of compounds.

III.A.3.b Choice of protection system

In the case of modification of an existing installation, the use of an ALARA approach for this type of occupational exposure requires the identification of the main sources of contamination and the most penalising types of work operation. In practice, however, this identification generally can only be made with recourse to both feedback and a specific programme of measurement of the concentrations inhaled that are sufficiently representative of the conditions of exposure. It is then possible to measure the expected efficiency of the protective actions envisaged by used ex post facto concentrations and by modelling the exposure and internal dose.

III.A.3.c Assessment of exposure levels while work is in progress

Unlike the external dose rates customarily encountered in nuclear installations, internal exposure arising from the inhalation of radioactive compounds cannot be directly measured in terms of absorbed dose by means of an instrument such as a dosimeter. In order to gauge such exposures, they must be estimated on the basis of a measurement of physical parameters (activity or chemical concentration) that describe the exposure. This therefore requires both the deployment of a surveillance system (either collective or individual), which sensitivity must therefore be assessed, and the use of models (for which results accuracy has already been discussed above).

The following three methods of surveillance have been (or may be) put in place to monitor exposures:

1) The first consists of collective air sampling systems. In order for this measurement method to be representative, the concentrations of airborne contaminants at each workplace must be relatively stable over time so that the inhaled concentrations are comparable with the concentrations measured. This is rarely the case, however, in cases where the contamination is caused by the activity of the operator. This method requires not only measurements of airborne concentrations that are representative of the air inhaled, but also an estimate of respiratory flow rate and the time spent by employees at different workplaces.

2) The second method consists in the installation of individual air-sampling systems. With this method, the uncertainty primarily lies in the difference between the concentrations inhaled and the concentrations measured, and the estimated respiratory flow rate. This discrepancy will be minimal provided that the sampling point is sufficiently close to the entrance to the respiratory tract and that the sampling flow rate is sufficiently high to allow representative sampling. In this case, the uncertainty overdosimetric estimates is much lower than in the case of collective air sampling systems, which is one of the strong points of this means of surveillance.

3) The third method consists in individual surveillance by means of biological measurements (measurement of urine excreta or measurement of residual pulmonary activity.

The measurement of urine excreta is based on the assumption that it is possible to determine the activity inhaled corresponding to the excreted activity measured. The accuracy of this estimate, which requires knowledge of the temporal profile of absorption (isolated, chronic, etc.) between two successive measurements and sometimes requires account to be taken of the activity inhaled during the previous measurement intervals, will be higher if measurements are made at shorter intervals. It should be noted, however, that besides the problem of samplerepresentativeness, the uncertainty mainly lies in the systemic urine excretion function and in the determination of a realistic time profile for exposure.

The measurement of residual pulmonary activity is based on the assumption that it is possible to determine the activity inhaled corresponding to the pulmonary activity measured, assuming that a time profile for absorption exists between two successive measurements. In this case, the uncertainty primarily lies in the determination of a realistic time profile for exposure. Here too, taking measurements at frequent intervals and, if necessary, taking account of the activity inhaled during the previous measurement intervals can make the estimate more realistic [10].

III.A.3.d Controlling risk in the course of work operations

With regard to internal exposure, French regulations currently in force (Decree 88-662 of 6 May 1988) specify both annual limits of intake and annual limits for concentration in ambient air. It should be noted that the Decree provides for both surveillance of the working environment and individual monitoring of workers likely to be exposed to annual intakes exceeding 3/10 of the annual limits of intake.

Collective air-sampling systems are therefore installed at various points in workshops. To meet the requirements with regard to individual surveillance, biological measurements are carried out at regular intervals. It should be noted, however, that in most cases the measurements of pulmonary retention obtained are below the detection threshold (150 Bq for insoluble uranium) and as a result the dose is usually not calculated. However, if it is assumed that, in the case of a person examined twice a year, the measurement of residual pulmonary activity is just slightly below the detection threshold, then the corresponding annual dose can vary from 10 mSv to 40 mSv (according to the intake time profile considered).

III.A.3.e Vectors of progress and unwanted effects

At present, the adoption of an ALARA approach in the case of exposure through inhalation to natural uranium compounds is hampered by the need to produce sufficiently realistic data to be able to assess the exposures associated with the different tasks performed by operators. Against this background, a number of experiments using complementary measuring systems, given the levels of accuracy and sensitivity associated with each of them, are currently being carried out. It would therefore seem that with regard to the adoption of an ALARA approach:

Stationary air-sampling devices are a good means of making an initial identification of the main sources of contamination and the tasks that are potentially the most penalising.

Portable, high-flow rate devices are a suitable means of estimating individual exposures and of identifying the most penalising tasks.

Measurements of urine excreta are a useful means of validating estimates of individual exposures made on the basis of air-sampling methods.

III.A.4 Basis for comparison of occupational risks

III.A.4.a Predictive risk-assessment

The predictive risk-assessment presupposes that the characteristics of the source of exposure and the exposure conditions are known. It is possible to model these risks provided that the exposure is the result of known and reproducible physical phenomena and working procedures (external exposure to IR). In the observed cases (asbestos, internal exposure to IR), the internal exposure is closely related to the activities performed and in practice is extremely difficult to predict. In addition, the significant variability of working conditions and changes of workplaces are not favourable to the elaboration of models. The predictive risk-assessment is therefore based on an ad hoc study itself based on a measurement programme that in some cases is supplemented by the modelling of doses (internal exposure to IR) and the experience feedback; the knowledge gained from other work situations can provide information on the exposures associated with different existing operating procedures (asbestos, internal exposure to IR).

III.A.4.b Choice of protection system

The choice of protection system is determined on the basis of an assessment of the relative importance of the risks in the working environment (asbestos risk of cancer versus risk of fall or electrocution) and makes use of the most effective actions available. These choices take account more or less explicitly of the technical and economic feasibility of the actions. The choices therefore require priorities to be identified and the effectiveness of existing resources to be assessed. The identification of priorities requires the prevention experts to provide an expert judgement, which is based in particular on the experience feedback and, when possible, ad hoc measurement programmes.The determination of the most cost-effective protective actions can therefore be based on an economic appraisal as part of an ALARA approach (internal and external exposure to IR), or may consist in the application of good practices in cases where it is difficult in a real working situation to assess and strike a balance between the risks associated with each possible option (asbestos).

III.A.4.c Assessment of exposure levels while work is in progress

Assessing individual exposure levels makes it possible to monitor trends in such exposures over time and to compare them, in particular, to the permissible exposure limit. This requirement is met in the case of external exposure to IR in nuclear installations, which provides an ideal model of surveillance in which the measurements taken directly and without interruption at the workplace provide a direct indication of exposures.

In the other cases studied (internal exposure to IR, asbestos), there is no measuring system for individual exposures. A system of surveillance through repeated ad hoc measurements (concentration of asbestos fibres in the ambient air in the workplace and degree of absorption of radionuclides, either through gamma measurements or through measurement of biological indicators) or through continuous monitoring of ambient air (concentration of radionuclides in the workplace atmosphere) is put in place.

This type of surveillance, however, cannot readily take account of individual exposure levels in that there are concentration peaks that might not be detected by an intermittent surveillance system or levels that are occasionally below the detection threshold of the measurement instruments (biological indicators of internal exposure to IR). The measurements made may be extrapolated in order to allow comparison with the PEL, but such assessments remain uncertain (asbestos). Another additional form of surveillance may be used to counter these inadequacies in the form of a standard table of exposure by workplace or by task, based on national measurement campaigns (asbestos). The data given in this statistical table allow the overall knowledge about exposures to be correlated to the local exposure characteristics of a given population.

III.A.4.d Controlling risk in the course of work operations

In the three cases studied, the control operations are not aimed solely at ensuring compliance with the PEL. It is known that in the case of exposure to IR, the main objective is not to comply with the limit dose but to reduce doses below that limit, in accordance with the ALARA approach. In the case of exposure to asbestos, it has repeatedly been shown how difficult it is to measure individual exposure.

Control operations are therefore aimed at obtaining a more general assessment of the prevention approach adopted by enterprises. In the case of external and internal exposure to IR, the aim of the prevention authorities is to determine whether the ALARA approach has been properly followed, which is by no means a straightforward task since it is necessary to evaluate the resources deployed and not simply the quantitative results obtained. This form of control is ultimately not very different to that used in the case of exposure to asbestos. In the latter case, it is not by the direct measurement of the exposures that the regulatory authorities can approve compliance with the PEL, but rather by verifying the adoption of good practices.

III.A. 4.e Vectors of progress

The ALARA approach has given rise to development of operational systems that have been tried and tested in the management of external exposure to IR, namely predictive dosimetry, supplemented by a real-time follow-up of exposure, data logging system and experience feedback, assistance in the choice of protective action on the basis of cost-benefit or cost-effectiveness analyses, with reference where applicable to man-Sievert monetary values. This approach, however, has still not yet been adopted in all nuclear installations. The development of this approach is based in particular on a clearer definition of its framework and procedures for application and also on greater involvement of the actors concerned.

In the examples of internal exposure studied, there are a number of metrological problems associated with the use of this approach. In the case of IR, improvements are expected in the development of methods of assessing internal dosimetry, which in France are still considered to be covered by medical confidentiality. In the case of asbestos, the development of continuous monitoring methods would be a significant advance. Other avenues are be tried out in parallel (asbestos) in order to overcome modelling difficulties and to focus risk management on improved codes of ***good*** practices and the experience feedback (knowledge of exposures by workplace, knowledge of exposures by protective equipment).

III.B Environmental carcinogenic risks

III.B.1 Airborne nickel contamination

Following the adoption by the European Union of a framework directive on air quality assessment and management in 1996 (Air Quality Assessment and Management, AQA/M directive), it is now necessary to take account of the air pollution associated with discharges of nickel into the environment. Nickel is one of the 13 agents singled out as priority indicators of air pollution. There are plans to issue a daughter directive (1999) which will establish an air quality standard for nickel (Air Quality Standard, AQS), and the values for nickel concentrations in ambient air currently under discussion range from 10 to several tens ng/m3. In France, the provisions of this standard was due to be incorporated into the law on air and the rational utilisation of energy of December 1996 (French law on air quality), notably with regard to the drafting of regional air quality plans. Alongside this environmental approach, the air quality standard should be taken into consideration for the setting of limit values for discharges from installations as part of the recommendations concerning the “best available technologies”, in accordance with the European framework directive on the integrated pollution prevention and control of 1996 (IPPC directive).

Thus a formal link already exists between the two approaches (by installation and from an environmental standpoint); however, to the extent that the two directives as well as the French law on air quality are in the process of being put in place, the analysis proposed below will remain limited, in certain respects, to that of the “intentions” or objectives assigned to the various actors by the European directives and French legislation.

III.B.1.a Approach by installation

Procedures for the management of waste discharges

In view of the large number of sources of nickel emissions to the ambient air, special efforts have been made to identify sources and quantify emissions at both European level (notably through the CORINAIR programme) and at the national level in France (survey carried out by CITEPA). It is also worth mentioning in this respect two international projects that are currently in progress, namely the OSPARCOM (Convention of Oslo and Paris for the Protection of the North Sea and North Atlantic) and UNECE-LRTAP (United Nations Economic Commission for Europe/Convention on Long Range Transboundary Air Pollution).

The first programmes were set up in the 1980s, notably with regard to SO2, and led to the establishment of a classification for the various sectors concerned with regard to the analysis of emissions: the ATMOS/PARCOM classification. The application of this assessment procedure to discharges of nickel to the atmosphere made it possible to distinguish between three major industrial sectors the nickel production industry, the stainless steel production industry and installations burning heavy fuel oil. Factors were then estimated for discharges to the environment from each type of installation. These factors were a function of both the technologies adopted and the raw materials used (significant variations were noted according to the source of the heavy fuel oil used).

In practice, in order to estimate the amount of nickel discharged into the environment, it is possible to made use of direct measurements made at installations (as part of the surveillance plans applicable to industrial installations) with regard to the nickel production industry and, in part, the stainless steel industry, while direct measurements of this kind are not available for other sectors (since nickel is not a major emission source in such installations, it is not measured unless there are specific measurement programmes in place). In respect of the latter, therefore, the emission factors published in the literature (or obtained from specific case studies) are used. This approach has been used to estimate the quantity of nickel annually discharged into the atmosphere in France (estimated for the mid-1990s) [11]:

Nickel production industry	5 t
Stainless steel production industry	10 t
Heavy fuel oil combustion[18]:	
• Power generation plants	18 t
• Industrial combustion	47 t
• Tertiary/residential combustion	45 t

This inventory reveals the significant volume of emissions from a large number of sources burning heavy fuel oil, primarily in industry. However, although the nickel emissions from nickel production and stainless steel industries are of lower magnitude, they are limited to about 10 emission sites.

Besides the existence of a large number of sources, once it is possible to estimate the quantities released from different points, it would be helpful to develop a model for transfers of nickel to the environment. Such a model is currently being developed but will be highly complex in that the concentration of nickel in the environment will be governed by:

- The large number of sources (given the contribution made by heavy fuel combustion).
- The effect of re-suspended particles.
- The transportation of particles over long distances (possible impact of pollution originating several thousand kilometres away).

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18. In the case of heavy fuel oil combustion, it must be highlighted that current programme of reduction of S02 emissions may have significant indirect effects on nickel emissions.

Control resources and systems

Discharge measurement programmes

Two types of installation need to be taken into consideration:

- Industries producing nickel and those which make significant use of nickel (stainless steel production industry).
- Installations using heavy fuel oil.

The former are regularly inspected as part of the surveillance of installations classified for the environmental protection purposes, and in this particular case nickel is explicitly identified in licensing applications for installations. In contrast, for all sources associated with heavy fuel combustion, no surveillance is carried out at present to the extent that, for each installation (considered separately), nickel emissions remain limited and are therefore not counted as one of the substances to be monitored. This situation poses the problem of the linkage between surveillance of specific installations and concentration in the environment in the case of multiple emission sources.

Use of the best available technologies

The IPPC directive provides for actions aimed at preventing or, where that is not practicable reducing emissions in the air, water and land from polluting activities specified in Annex 1, including measures concerning wastes, in order to achieve a high level of environment taken as the whole.

The operating licence, issued by the Prefect with technical support provided by the DRIRE, must specify the limit values for discharges of polluting substances likely to be emitted by the installation concerned, after account has been taken of the potential transfer of pollution from one medium to another (water, air and ground) and after consideration of the technical characteristics of the installation concerned, its geographical location and local environmental conditions. The aim is not to specify use of a generic technology, but to make a genuine effort to identify the best available technology (BAT) applicable in the context in question and under conditions that are economically and technically viable.

The discharge limit values must be principle be capable of being discussed on the basis of the best available technologies after consideration has been given in particular to the geographical location of the installation and local environmental conditions. Such a situation must be capable of accommodating negotiations at the local level in order to take account of the local impact of discharges[19]. In the particular case of nickel, the IPPC directive concerns nickel production installations and the stainless steel production industry and disregards pollution caused by the combustion of heavy fuel oil.

III.B.1.b Environmentally-based approach

Retrospective assessment of exposure of the public

In order to be able to identify the exposures associated with nickel discharges to the atmosphere, it is first necessary to establish a regular supply of information regarding the concentrations present at various points. But it should be stressed that the measurements currently made are highly sporadic in

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[19] Taking account of the long range transport of heavy metals (notably nickel), the elaboration of protection policy should address the mitigation of the long range ortransboundary releases impacts. Policies being elaborated at a local or a regional level, a trade-off should be made at the national or European level.

terms of both the sampling points and the time intervals at which they are made. However, the local and seasonal variations are extremely large. Thus the studies carried out on nickel concentrations in the local environment show that these concentrations are the outcome of complex dispersal patterns involving not only artificial sources and natural local sources, but also meteorological parameters and the re-suspension of particles as a result of human activity or wind action (long-range transport). The latter phenomenon may help to increase nickel concentrations at distances of up to several thousand kilometres.

At present, relatively few measurements are made of nickel concentrations in the environment in that no priority has been given to this substance in measurement programmes. The few specific measurement campaigns carried out to date have been aimed at determining pollution levels in urban areas. They provide information regarding airborne nickel concentrations only for a few regions. In France, nickel concentrations have been specifically measured in Paris, Strasbourg and Rouen.

The data available with regard to European countries suggest the following orders of magnitude for concentrations in urban, industrial and rural areas [11].

A detailed analysis of airborne nickel concentrations in Paris carried out by the Laboratoire d'Hygiène de la Ville de Paris from 1976 to 1989 illustrates the difficulties involved in identifying, through these measurement programmes, the specific contribution of local emissions. This analysis suggests that they contribute significantly to long-range transport.

Zones	**Order of magnitude of concentrations (ng/m^3)**	**Average Value (ng/m^3)**
Urban	3 – 25	11.5
Industrial	2.3 – 50	7
Rural	0.7 – 5.5	2.5

Control resources and systems

As mentioned above, measurements of nickel concentrations in the environment currently remain highly restricted in scope and are not part of a monitoring programme but carried out simply for information. Changes in the European regulatory framework should eventually lead to the creation of a system of measurements of the concentration of various chemical compounds (including nickel) in the ambient air at the regional level (Directive AQA/M). France has already passed legislation on air and the rational use of energy which provides a general framework for the organisation of systems for managing the risks associated with the pollution of air by nickel. The key element in this is the drafting of a regional air quality plan.

One original feature of this plan that merits attention is that it proposes to assess the impact of air quality on health. Its aim is to establish priorities for both improving air quality and developing the surveillance of, and knowledge about, the impact of air pollution on health. In particular, priority will be given to applying epidemiological data collected at national and even international level to the conditions prevailing at the regional level. On the basis of the values used to calculate the increased number of deaths from lung cancer attributable to airborne nickel (1.4 x 10-9 deaths per year x [ng/m3]) and an average annual value for Europe of 10 ng/m3, the risk amounts to around 4-5 additional deaths from lung cancer a year out of a population of 327 million people[20].

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[20] It should be noted that the highest nickel concentration levels in ambient air that were measured during these last few years from samples collected over one or two days are about 5 times higher.

Priorities will be set at the regional level for the main sources of air pollution. As part of this process, nickel, as soon as the daughter directive has been adopted at the European level, may be taken into consideration in regional plans provided that air pollution is given priority at the regional level. In addition, decisions regarding policy directions at the regional level must take account of the cost and effectiveness of any actions that might be taken to prevent or reduce air pollution. Lastly, plans will be subject to a public enquiry and information regarding them will regularly be made available to the public and the European Commission. The entire plan must be reviewed every 5 years.

It would seem that the procedure adopted for the drafting and implementation of these regional plans, although it will have to prove its worth, should amount to an ALARA type approach towards management of the risks associated with air pollution, placing the emphasis on the setting of local priorities which take account of the economic feasibility of the actions proposed. Furthermore, in view of the actors involved in the drafting and follow-up of the plan, there would appear to be scope for negotiation at the regional level.

III.B.1.c Linkage between the two approaches

In principle, the two approaches set out in the IPPC directive, the AQA/M directive and the French law on air quality are complementary and are both based on:

Recommendations, at the central level, in terms of references with regard to the best available technologies and the values for concentration in the environment.

A local approach to determine the technical feasibility and potential local impacts and to establish priorities for achieving air quality objectives.

However, although the development of negotiations at the local level over priorities regarding the improvement or conservation of air quality brings the various actors involved together and makes it possible to establish a linkage between the two approaches, it is important to bear in mind that models of the dispersal of discharges to the atmosphere are not sufficiently advanced at present to allow predictive assessment of the anticipated efficiency of reductions in emissions from a given source at the local or even regional level. This limitation may make difficult overall identification of "polluters" at a local level and, as a result, may not allow the most effective protective actions to be chosen.

III.B.2 Exposure of the public to IR as a result of waste discharges from Nuclear Installations (NI)

III.B.2.a Approach by installation

Procedures for managing waste discharges

The management of waste discharges from " nuclear installations" (e.g. installations that are part of the nuclear fuel cycle) in France is based, as in many other countries, on a licensing system in which operators submit requests for permission to make discharges. In support of such requests, operators submit arguments at two levels:

- The efficiency of the technical processes used to treat waste makes it possible to significantly reduce discharges of radionuclides[21]. In general, the operator presents the proposed system without comparing it with other alternatives. The basis on which the technology has been

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[21] That is to say the radionuclides contained in the discharges: notably, uranium decay chain, fission products, transuranic actinides.

chosen remains implicit, and the solution proposed is mainly based on technical, historical and economic considerations.

- A predictive calculation of the dose received by the persons in the so-called reference group[22], due to the waste discharges, shows that the doses are in most cases low, if not very low. This calculation is based on models simulating the mechanisms through which radionuclides are dispersed and reconcentrated in the environment and finally the associated human exposures. Even if account is taken of the exposure resulting from other nuclear activities, the annual dose to these persons must not exceed the dose limit for the public.

The approach adopted combines considerations relating to the "best practicable technologies" or the "best available technologies at an economically acceptable cost" with considerations relating to the dosimetric impact of discharges.

The first level of implementation of the ALARA approach by operators concerns the justification of the level of waste discharge submitted to application. Thus, from the standpoint of the authorities, the acceptability of the solution proposed by the operator is therefore based on both a technical evaluation[23] of the waste treatment processes and an evaluation of the dosimetric impact on the populations subject to the greatest exposure. It is a type of ALARA approach based on the design of waste treatment systems. Accordingly, the justification of discharge licence applications is mainly based on the level of activity of the wastes discharged.

In the case of most installations, calculation of the doses arising from such discharges shows that the maximum doses are 1 to 2 orders of magnitude lower than the annual dose limit for the public. This confirms that the main concern is to make use of the "best available technologies at a reasonable cost", by taking account of the characteristics of the site and not by attempting to comply with the dose limit, which in fact encompasses all exposures other than those of natural or medical origin. Licences for discharges from installations, which represent the maximum permissible envelope under normal operating conditions, may be treated as constraints with regard to actual discharges.

The second level at which the ALARA approach is implemented by operators concerns trends in actual discharge levels. In general, there is a trend decline of the volume of discharges arising from the operation of installations. The mechanisms responsible for this downwards trend is often presented by operators as the outcome of application of the ALARA approach. In fact, the operator's approach reflects his concern, in a changing context, to achieve a "reasonable" compromise between several objectives: the account taken of the particular sensitivity of populations with regard to discharges of radioactivity to the environment, in some cases the desire to project a positive image or to improve his ranking in terms of international comparison between operators, the integration of experience feedback, technical progress and good practices as part of a general "quality" approach, the need to reduce costs in order not to erode economic competitiveness. To some extent this represents a pragmatic form of ALARA approach, which is pursued during the operating stage of nuclear installations. It should be noted that the approach adopted by the operator in this instance diverges significantly from the formal optimization procedure laid down by the ICRP (in general, the processes chosen are not compared with alternative solutions and the performance indicator used is the activity released and not the collective dose, whereas in principle the former is a key element in the formal optimization framework).

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[22] That is to say homogeneous group of people receiving the highest mean individual dose among the whole population exposed to a given installation.

[23] The economic assessment remains implicit. But the experts in charge of reviewing the waste discharge licence application take into account economic considerations when they are reluctant to ask systematically for additional waste treatments, even if technically feasible.

Control resources and systems

Discharges of (radioactive and chemical) wastes from NIs in France must be authorised by the relevant Ministry following examination of the application by the operator at both the national and local level. Applications by NIs in France are examined by the DSIN with expert advice provided by the OPRI and the IPSN. The latter two agencies are called upon to give a technical advice with regard to the justification of the levels of discharge for which authorisation is required. The IPSN evaluates the two components of the argument presented by the operator. It analyses the file and after a discussion of the technical aspects with the operator gives an advice as to whether or not the waste treatment processes and waste management and sorting procedures are appropriate, given the radioactive waste flows generated under normal operating conditions or during certain operating incidents. In addition to which, the IPSN checks that the assumptions and calculations used to determine the doses received by the persons in the reference groups are justifiable. The final outcome will take account of these two complementary aspects. It is therefore apparent that the linkage between justification of the levels of discharge and the dosimetric impact the individuals who receive the greatest exposure to discharges is an integral part of the process of assessing the impact of discharges from NIs. In this context, the assessment for the purpose of licensing discharges makes reference to the best available technologies by taking account of local situations and, implicitly, economic considerations.

A number of restrictions are placed on the operator with regard to the verification of discharge levels. Operators are responsible for surveillance (self-monitoring) while the OPRI periodically takes samples from tanks and various emission sources for analysis. The OPRI also checks that the regulatory inventory logs of discharge volumes are kept up to date.

In addition, the discharge licence application is at the same time the subject of a public enquiry procedure. This procedure offers the populations residing in neighbouring communes, and in particular environmental protection associations, to read the application and to voice their criticisms or make suggestions. A concluding report explaining the grounds for the decision taken with regard to the operator's application is then drawn up by an investigating commissioner and sent to the communes concerned, the local authorities and the DSIN.

III.B.2.b. Environmentally-based approach

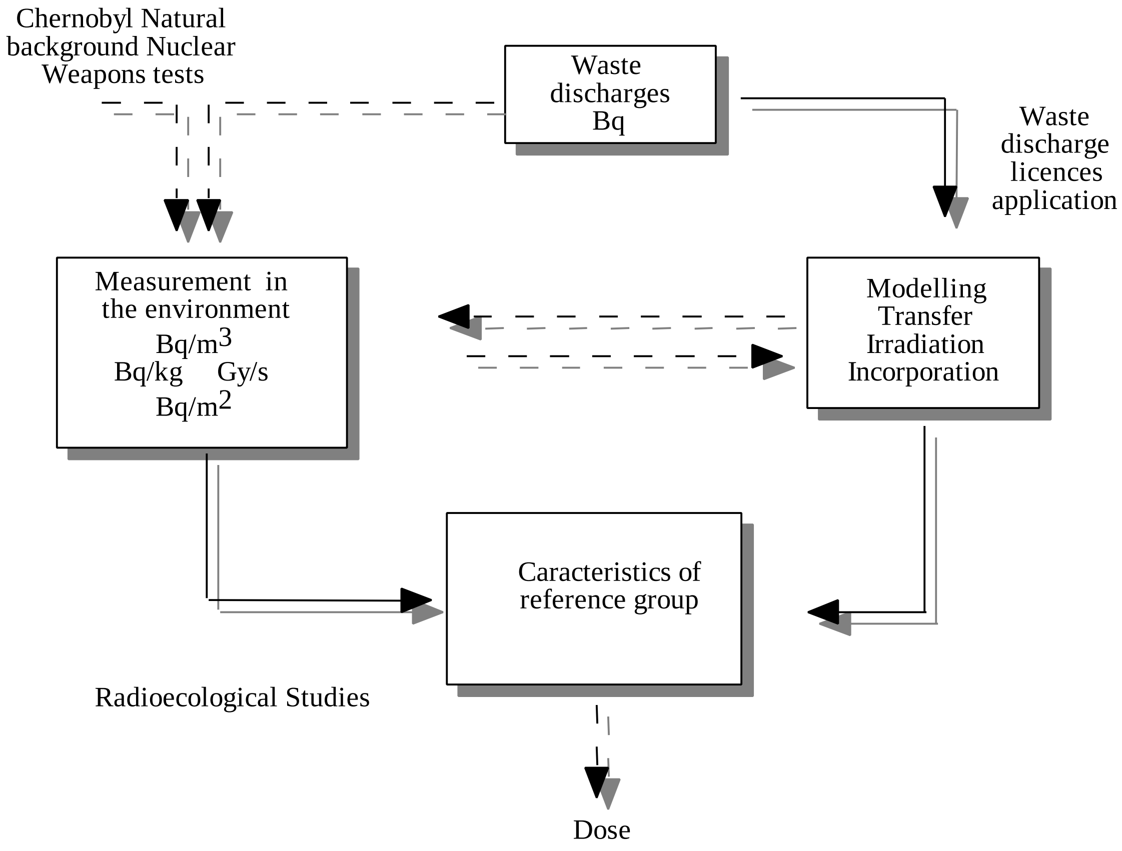
Retrospective assessment of public exposure

In the case of discharges from nuclear installations, the environmental approach cannot be dissociated from the approach by installation and the assessment of the doses associated with discharges is made when discharge licence applications are submitted. Local populations tend to ask for verification that the health impact of installations is "negligible". For statistical reasons, epidemiological studies cannot show whether there is any increased risk that could be related to waste discharges from NIs during normal operation. This problem is side-stepped by carrying out an ex post facto assessment of the dosimetric impact on the reference groups. In such cases the assessment of the dosimetric impact takes account of individual doses, since the collective exposure is not generally central to the assessment process in the case of the exposure received by the public in France. Only the reference groups are effectively taken into consideration, with the notable exception of the work carried out by the Radioecological Group of the Nord-Cotentin which attempts to assess the doses received by population groups residing near to several nuclear installations. It should be noted, however, that practices vary from one country to another. In the United Kingdom, for example, impact studies include a calculation of the collective dose.

At present, actual discharges from installations, which are generally well below the maximum permissible levels, represent annual individual doses of the order of several tens μSv for the reference groups (i.e. 1 to 2 orders of magnitude below the annual dose limit for the public). This value corresponds to an increased lifetime individual health risk of the order of 10-5 to 10-4 for the persons subjected to the highest exposure levels.

Assessment of the individual dose received by the reference groups makes use of two complementary methods that are represented schematically in Figure 1. The first method consists in measuring the concentration of radionuclides in the environment and estimating the subsequent contamination of the population groups concerned, after taking account of their geographical location and the use they make of the environment. The other method consists in calculating dose rates, on the basis of data on the actual discharges from a given installation, by means of transfer models.

Figure 1. **Different approaches used to assess the doses received by the public**



Control resources and systems

Data on radioactivity levels in the environment are systematically collected in accordance with regulations on the monitoring of discharges and, where applicable, as part of ten-yearly radiological inventories[24]. The monitoring of radioactivity levels in the environment is the responsibility of the

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[24] Operators provide complementary data through radioecological impacts site studies performed by expert organisations, such as IPSN and CRII-RAD.

operator, who carries out such monitoring in accordance with the procedures laid down by the OPRI. The latter's officials carry out inspections in the environment of the installations. The inspections in this case are aimed at verifying whether licence requirements are met in terms of average activity concentration added to rivers and to the atmosphere (after dispersal, at ground level, beyond 1 000 m of the emission point).

The calculation of doses (through ingestion, inhalation and external exposure) attributable to an installation on the basis of environmental measurements is not an institutionalised practice at present. In some cases, however, such calculations are required by the Local Information Commissions in place around nuclear sites or set up in response to "emergencies", as in the case of the leukaemias reported in the Nord-Contentin. In the latter case, the work carried out goes beyond the simple doses reconstruction. It was carried out, at the request of the Ministers responsible for the environment and health, by working parties made up of operators and experts from institutional organisations (OPRI, IPSN, CNRS) and "independent" groups (CRII-RAD, GSIEN, ACRO)[25], reporting on results to various local bodies including the La Hague Special Standing Commission on Information.

III.B.2.c Linkage between the two approaches

In the case of NIs, the approach by installation (technical and economic justification of licensed waste discharges) clearly cannot be dissociated from the environmental approach, which can itself be broken down into two components (predictive assessment of dosimetric impact of licensed discharges and retrospective assessment of the dosimetric impact of actual discharges).

The examination of applications for waste discharge licences provides a "bridge" between the two approaches. This bridge, however, is sometimes in place ex post facto, in which case an attempt is made to track measurements in the environment to actual discharges from a given installation. This method poses a number of problems:

The observed concentration levels are often below the detection threshold of the methods and instruments currently used.

The measurements encompass all of the activity present in the environment, irrespective of its origin. It therefore follows that the measurement represents not only the impact of the installation concerned, but also that of background radiation, fall-out from earlier atmospheric testing of nuclear weapons, the Chernobyl accident, discharges from neighbouring installations, etc.

The procedures designed to "track" discharges from a given installation lead therefore to highly uncertain results at present.

The overall process of controlling the health impact of NI discharges has two complementary aspects. From the standpoint of the actors involved, the approach by installation and predictive assessment of the dosimetric impact at present mainly involves the authorities, operators and institutional experts. The environmental approach, in terms of retrospective analysis, would seem to offer the local population and environmental protection associations an opportunity to play a part, as yet poorly defined, in the process. In view of this situation, the expert assessment instead of providing definite solution is notably submitted to a contradictory debate in the presence of the parties concerned including non-institutional organisations (the "independent" experts).

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[25] Commission de recherche et d'information indépendantes sur la radioactivité, Groupement de Scientifiques pour l'information sur l'énergie nucléaire, Association pour le contrôle de la radioactivité dans l'Ouest.

III.B.3 Preliminary comparison regarding nickel and radioactive waste discharges

III.B.3.a Approaches by installations

Radioactive waste discharges to the environment are clearly identified and the main sources of such discharges are nuclear installations in the fuel cycle operating under the supervision of a national authority (DSIN).

The management of waste discharges from nuclear installations is based on an integrated two-fold approach in which account is taken of the technological process available for treating waste at an economically acceptable cost and an assessment is made of the dosimetric impact of discharges.

The waste discharge licence application is also submitted to public enquiry (calling for comments notably from local populations and environmental protection associations).

In the case of nickel, the source of airborne pollution and its impact on the environmental are harder to determine. Admittedly the nickel and stainless steel production industries are both major generators of nickel pollution and as such are closely monitored (their status as classified installations places them under the supervisory care of a regional authority, the DRIRE). Naturally the regulatory framework includes a standard relating specifically to nickel which applies to nickel discharges from such installations. This standard provides for a discharge limit to be set locally by the DRIRE on the basis of the best technologies available and in accordance with the specific characteristics of the plant and its environment.

However, a large share of nickel discharges is accounted for by a large number of “minor” sources, each generating a small amounts of nickel through the combustion of heavy fuel oil. For these sources, reducing nickel releases to the environment is not a priority in terms of the management of individual installations, whereas all these sources as a whole significantly increase the concentration of nickel in the ambient air. Given the large number of sources involved and in view of the complexity of models used to simulate discharge dispersal processes, it is difficult to establish a relationship between discharges and concentrations.

III.B.3.b Environmentally-based approaches

Retrospective assessment of public exposure

Because of the lack of a model that can be applied directly to nickel discharges, determining public exposures requires the use of programmes to measure the concentration of nickel in the ambient air in “higher risk” zones.

In the case of ionising radiation, on the contrary, exposures can be calculated retrospectively by means of transfer models based on actual discharge data. In some cases it is even possible to supplement this assessment with measurements of concentrations in the environment.

Despite these differences, it is interesting to note in both cases the public demand for a follow-up of the health impact on populations on the basis of epidemiological studies, although for statistical reasons such studies could not probably establish the existence of a possible increased risk of cancer attributable to routine discharges to the atmosphere.

Control resources and systems

In the case of nickel discharges, the drafting of regional air quality plans provides the various local actors with a genuine transactional forum for the determination of protection policies. Policy formulation at the local level should be aimed in particular at setting priorities for compliance with the future exposure limit value[26] by taking account of the socio-economic fabric and the characteristics of the local environment. This therefore amounts to a management based on exposure level (and not the amount of discharge): local exposure levels (measured here in terms of concentration in the ambient air) will determine the choice of measures best suited to reducing discharges locally.

In the case of IR, the assessment of future doses or measurements in the environment are used to supplement the analysis of discharges. They are not central to the formulation of protection policies[27].

It would therefore seem that negotiation at the local level should be the key component of protection policy formulation in the case of nickel discharges. Whereas for IR the account taken of exposure levels reflects more the desire to verify that the choices made in the approach by installation are properly founded.

III.B.3.c Linkage between the two approaches.

In the case of ionising radiation, the ability to model, and therefore to track, discharges makes it possible to create a continuum between the environmental approach and the approach by installation, whereas it is primarily through the environmental approach that protection actions should be designed in the case of nickel discharges.

This difference, which is primarily of a technical nature (due to the problems involved in modelling airborne nickel concentrations), means that measurement of the environmental impact is made a central issue in the case of nickel and therefore tends to open up the local negotiation to actors whose concerns relate to health, the environment and even regional development. The negotiation therefore tends to be broader and to embrace criteria other than those relating to technical and economic aspects of waste discharges. Although nickel and radioactive waste discharges are ultimately managed through use of BAT criteria, it should be noted that account taken of actual exposure levels is currently an essential element in the formulation of policies towards reducing the concentration of nickel in the environment.

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[26] The exposure limit value for nickel concentration in ambient air is expected shortly from the European Commission.

[27] However, only in a few cases, the dose reconstruction may appear as an essential stake for the various local actors (e.g. Radioecological Group Nord Cotentin).

CONCLUSIONS

In conceptual terms, the management and assessment issues in the three cases discussed would seem to be very similar. The dose-effect relationships based in the case of ionising radiation (IR) on the follow-up of survivors of the bombing of Hiroshima and Nagasaki are comparable to the dose-effect relationships established for asbestos and certain nickel compounds based on the epidemiological study of various situations involving occupational exposure. It is therefore generally accepted, as part of the management of cancer risks, that it is legitimate to extrapolate these relationships to low levels of exposure.

Note should nonetheless be taken of the restrictions to the scope of application of the conceptual approach: exposure-risk relations for asbestos are not applicable to so-called sporadic exposures (exposure peaks, followed by a period of very low or zero exposure); similarly, the exposure-risk relation for nickel does not concern all nickel compounds.

Subject to the above limitations, a comparison can in principle be made of protective actions on the basis of the optimisation principle, as defined in the case of IR. In addition, the existence of a level of residual risk is accepted in all three cases, in that protective action is not aimed at achieving zero risk.

From the regulator standpoint, it may be seen that the dose limits for ionising radiation do not have the same status as exposure limit values (PELs) for asbestos and nickel.

In the case of IR, reducing exposure to a level that is within the limit is not in itself a sufficient objective (the limit is no more than a ceiling under which the risk is tolerated) and the emphasis is placed on reducing the exposure to a level that is as low as reasonably achievable (the ALARA principle, which enshrines the concept of an “acceptable” risk), which in most situations, and for most of the persons exposed, will result in an exposure level significantly below the dose limit.

In the case of occupational exposure to asbestos, the PEL corresponds to both the lowest level at which a statistically significant effect is observed (LOEL) for occupational exposures and the detection threshold for measuring systems used in the working environment.

In the case of public exposure to nickel compounds, the PEL is based on an increased lifetime risk of death of 10^{-5}.

In reality, the PELs for asbestos and nickel and extremely stringent. The fact that the regulations relating to these substances stipulate that exposure to carcinogenic substances must be reduced to the lowest level possible should not disguise the fact that achieving the PEL is in itself a highly ambitious objective.

In practical terms, the protective action in all three cases consists, finally, in making use of the means that amount to a “reasonable” compromise in respect of several criteria. The actors involved in the protective action usually attempt to reduce exposure levels by taking account of the technical resources available, the environment in which the latter may be deployed and, implicitly, the technical and financial capabilities of enterprises.

While there are a number of subtle differences with regard to the tools and approaches used, the ALARA approach in the nuclear sector is also to be found in the case of nickel in the attempt to find the "best available technologies", which must take account of environmental conditions. With regard to asbestos removal, despite highly prescriptive regulations which significantly limit the room for manoeuvre, there is nonetheless some leeway for determining what constitutes a "reasonable" mode of prevention. This margin makes it possible to avoid risk trade-off between asbestos carcinogenic risks and other risks (fall, electrocution). It should nonetheless be noted that even if such room for manoeuvre exists for the implementation of protection policies in different areas, the existence of PELs which establishes the risk levels to be achieved is such that it reduces flexibility with regard to regulation of the local risk, unlike the ALARA approach.

From the standpoint of the social risk-management, the various possible approaches (ALARA, ALARP[28], BAT) are not always sufficient to shape the social transactions needed to establish an risk of level acceptable to the parties concerned. These transactions are not based solely on the account taken of risks, but also on the context that is responsible for the risk-taking; the actors take account more or less explicitly, in accordance with the procedures implemented, of the interest that the activity responsible for the risk holds for both them and society. The elements involved here are the social and economic dimensions, as well as the cultural and symbolic importance attached to the activity; the risk cannot be separated from the context in which it is rooted. The social transaction relating to the drafting of the action plans to be implemented consists in establishing a forum for dialogue which offers the possibility of gradually establishing trust between the partners, to identify shared challenges and ultimately to achieve a common culture with regard to risk.

The higher the level at which the social transaction takes place, the greater the need to take account of the context. The management of occupational risks in the specific context of a given work site cannot be approached in the same way as management of the risk to the population as a result of waste discharges from several industrial installations.

In the former case, the attempt to secure a reasonable compromise may be based on relatively technical procedures (cost-benefit or cost-effectiveness approaches, agreement on certain rules of the art or good practices with regard to prevention), provided of course that a debate is organised beforehand between the parties with regard to the appropriateness of such procedures. Examples of such issues include the monetary value of a man-sievert (IR) or good practices (duration of work shifts on asbestos removal work sites, clothing procedures prior to entry into the area, etc.) or even the setting of air quality improvement objectives which reflect the local situation in the case of atmospheric pollution. These various examples illustrate the importance of placing approaches towards the formulation and evaluation of protection policies in their proper context.

In the second case, the attempt to define an acceptable cancer risk cannot be limited to the identification of reasonable solutions with reference to the ALARA, BAT, etc., approaches. It requires the exchange of many different points of view regarding the advantages and drawbacks (in which cancer risks are only one issue among many others) of the activity or activities concerned. In formulating protection policies, therefore, the adoption of an environmental approach is likely to encourage account to be taken of all the anticipated benefits of the activity and is not limited solely to the risks that it is likely to involve.

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[28] ALARP: As low as reasonably practicable.

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ANNEX I

THE CONCEPTUAL APPROACH

Introduction

This annex reviews the relevance and limitations of the various stages in the evaluation and management of risks in the case of exposure to asbestos, nickel[29] and ionising radiation (IR). The different steps in the procedure are - as regards the assessment of risk - identifying the hazard, formulating exposure-risk relationships, and evaluating the numbers exposed and the levels of exposure, in line with the approach described in 1983 by the United States National Research Council [1]. Besides these stages we may consider the assistance to decision-making arising from the evaluation of alternative risk management policies, notably using the scheme drawn up by the International Commission for Radiological Protection (ICRP) for managing radiological hazards [2,3].

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[29] In the following the term “nickel” will be used to denote nickel and its compounds.

1. THE CONCEPTUAL APPROACH USED FOR ASSESSING AND MANAGING RISKS ARISING FROM IONISING RADIATION

With regard to ionising radiation, radiation protection was organised fairly quickly with a view to protecting individuals from the deterministic effects. Thus radioactivity was discovered at the end of the last century (1895) and the first national directives concerned with radiation protection were formulated in the 1920s. At that time the risk management approach used involved adopting threshold values guaranteeing that there would be no deterministic effects. Quite apart from these effects, recognition of the fact that exposure to ionising radiation could cause cancer progressively resulted in the development of original methods for assessing and controlling risk that can cope with the question of the uncertainties associated with exposure to low doses. The following sections describe the approach worked out by the international community.

1.1. Identification of carcinogenic features

As early as the 1920s, an abnormally high incidence of leukaemia had been observed in individuals working with ionising radiation in the medical field. Around the same time, experiments on *Drosophila* revealed the possibility of genetic mutations (1927). However it was only after the explosion of the atomic bombs at Hiroshima and Nagasaki in 1945 that the stochastic effects were gradually revealed through epidemiological studies of the survivors. The first carcinogenic effect to be demonstrated was the higher incidence of leukaemia following exposure to ionising radiation, but other cancers were gradually recognised as being induced by radiation, such as those affecting the lung, digestive tract, colon, breast, and so on. Thus in 1958 the representatives of the international scientific community "officially" acknowledged that there was a risk of stochastic radiation-induced effects at levels of exposure below those of the deterministic effects. Even so, the risk management methods initially adopted to provide protection against the deterministic effects, which were based upon the setting of threshold exposure values, are no longer appropriate, and the question of formulating an exposure-risk relationship became a major concern of the international community as it attempted to formulate new methods of controlling radiological hazards more able to give protection from the carcinogenic stochastic effects.

1.2. Formulation of the exposure-risk relationship

1.2.1. Epidemiological studies[30]

The epidemiological studies that have been made of the exposure of the public to ionising radiation are of different kinds: they consist mainly of the investigation of those who survived the Hiroshima and Nagasaki atomic bombs, patients exposed in the medical field, individuals exposed in the course of their work, and people living in contaminated areas or where the natural background radiation is high [4].

The most exhaustive investigation, known as the "Life-Span Study", monitored the survivors of Hiroshima and Nagasaki, covering 93,000 survivors of the atomic bombs together with 27,000 people who

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[30] A detailed description of these investigations is given in the 1994 UNSCEAR report [4].

were living in Hiroshima or Nagasaki in 1950 but who had not been in these cities at the time of the explosions. The task of monitoring this population was entrusted to an American-Japanese commission: the Radiation Effects Research Foundation (RERF). Various factors that might explain the increased risk were reviewed: the influence of dose, age at the time of exposure, the time elapsed since exposure, sex, type of cancer, and so on. The results of the study are regularly revised as knowledge (or assumptions) about the dose levels delivered changes, and as the population monitored ages. It may be noted that the analysis by Pierce of the latest results (covering the period 1950-1990) reveals statistically significantly higher risk as from a dose level between 50 mSv and 200 mSv for the different radiation-induced cancers [5], but the study has been criticised as to the statistical significance of the higher risk observed in this dose range [6].

The cancers for which the "Life-Span Study" showed significantly higher death rates are leukaemia, cancers of the breast, bladder, colon, liver, lung, oesophagus, ovaries and stomach, and multiple myeloma. Monitoring of the incidence of cancers in this population shows appreciably the same results, except for multiple myeloma and cancer of the oesophagus for which the risk is not statistically significant. Two other cancers also show significant risk in the incidence study: those affecting the thyroid and the skin.

A substantial proportion of the epidemiological studies covers people irradiated during medical treatment, notably cancers sufferers treated by radiotherapy. The doses delivered in these cases are highly localised according to the treatment applied and can reach 40 to 80 Gy. These studies include the monitoring of more than 82,000 women with cervical cancer who were treated by radiotherapy between the ages of 30 and 70 in Canada, the United States, the United Kingdom, Denmark, Finland, Norway, Sweden and Yugoslavia (Boyce). There are also a number of studies covering for example the occurrence of breast cancer following irradiation for diagnostic purposes: these were women treated for pulmonary tuberculosis between 1930 and 1950 (Davis; Miller). Finally we may mention the study of a British group covering about 14,000 people exposed between the ages of 20 and 60 as a result of radiotherapy treatment for ankylosing spondylitis, resulting in substantial irradiation of the bone marrow (Darby).

As regards surveys of occupational exposure, we may mention those concerning the old but substantial exposure of uranium miners in the United States, Canada, Czechoslovakia and France, painters of luminous clock dials using radium paint, as well as radiologists (prior to the Second World War). More recent work includes the studies of workers in the nuclear industry in the United Kingdom and the United States, covering between 6,000 and 95,000 people. However studies of this kind are very difficult to conduct: although the number of people is large, the risks are difficult to demonstrate, owing to the low exposure levels. For this reason the groups available in different countries have been combined in order to give more statistical weight to the data, under the auspices of the International Centre for Cancer Research (ICCR).

As concerns exposure to background radiation, a few studies have been carried out in areas where this is high: the state of Kerala in India, the Andean plateaux, and areas where exposure to radon is very high (parts of the United States, the United Kingdom, China, Scandinavia and France). Of the instances of environmental exposure, we must also mention the populations exposed following accidental discharges into the environment. One study covers 28,000 people exposed at Techa River in the former USSR, following discharges of radioactive wastes from a nuclear weapons production plant. We may also note a current study of thyroid cancers occurring in children (in Russia, Belorus and Ukraine) exposed as a result of the Chernobyl accident.

It is believed that exposure to ionising radiation is liable to lead to the appearance of hereditary effects. Although such effects have not been detected in the epidemiological studies, a number of animal experiments reveal a stochastic risk that can show up either as a "marginal" malformation, or even death in later generations than the one exposed. The types of genetic damage regarded as important are genetic mutations (changes to the genes) and chromosome disorders (changes in the structure or number of chromosomes). As regards the degree of severity, about one-third of known hereditary problems can be regarded as severe and equivalent in seriousness to ICRP fatal cancers.

1.2.2. Modelling

Extrapolation to the whole of life

For extrapolating the additional risks observed in epidemiological studies to the whole of life, the ICRP recommends using a multiplication model for extrapolating solid cancers, because the natural mortality rates for these cancers increase with age, and they are incompletely monitored in the epidemiological surveys because they may emerge at ages very remote from the exposure. For leukaemia, the choice between an absolute or relative type of model for extrapolating additional observed risks to the whole of life is trivial, because the monitoring of this disease in epidemiological studies can generally be regarded as comprehensive, owing to its low probability of appearance at ages very remote from the exposure.

Extrapolation to low doses or dose rates

The models used for calculating the radiological hazard associated with radiation having low linear energy transfer (LET) are usually based on a linear extrapolation to low doses and dose rates of the dose-effect relationships observed at higher levels of dose and dose rate. The approach usually adopted is to utilise a linear dose-effect relationship of the following form at low doses or dose rates:

$$E = \frac{a'D}{\mathrm{DDREF}}$$

where:

E: the additional individual risk of death over the whole of life

DDREF: Dose and Dose Rate Effectiveness Factor

α': slope of the line

D: the cumulative dose received by an individual.

Although animal experiments suggest a wide range of values for the DDREF (between 2 and 10), further statistical analysis of human data suggests that this reduction factor should not be much greater than 2, or even 3 or 4 for certain tumours. Accordingly most national and international organisations (including the ICRP) cautiously use a value of 2 for the DDREF. It is recommended that this factor be used for calculating the radiological risk associated with doses below 0.2 Gy and dose rates below 0.1 Gy/h.

Transferring risk estimates to other populations

Although the mortality rate due to all types of cancers is relatively similar in the industrialised countries, the variations according to cancer type are still considerable. Moreover there is a difference in risk between the population studied, which sometimes involves people exposed several decades earlier, and the present population. However, in its 1994 report UNSCEAR stresses that although the question of transferring a calculated risk from one population to another is important and may lead to different evaluations for specific cancer sites, the differences in terms of the number of cancers expected are not always great (a maximum difference of the order of 30% for most countries) when one looks at the total risk (all cancers).

The UNSCEAR model

The most recent model for assessing radiation-induced risk, encompassing all organs, was published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) in its 1994 report. This model uses data from the survivors of Hiroshima and Nagasaki over the period 1950 – 1987. The model is based upon the absolute risk of leukaemia and a model based upon the relative risk for solid cancers.

As far as leukaemia is concerned, the absolute risk model used involves:

- A quadratic linear relationship with dose (D),
- A dependence on sex (s),
- A dependence on the time elapsed since exposure (t).

The formula used for the additional absolute risk (? AR) is the following (expressed as 10-4 per person/year):

$$? AR (D, t, s) = \alpha_{t,s} (D + \theta D^2)\, e^{\beta_{t,\, s} (25 - t)} \qquad (1)$$

where:

θ is a constant and α and β are parameters that depend on sex and on the time elapsed since the exposure.

For solid cancers, the model used is based on the relative risk with:

- a linear relationship with dose (D),
- a dependence on age at exposure (e),
- a dependence on sex (s).

The formula used for the additional relative risk (? RR) is the following (dimensionless):

$$? RR (D, e, s) = \alpha_s\, D\, e^{?\, \beta (e - 25)} \qquad (2)$$

where:

β is a constant and α is a parameter that depends on sex.

1.2.3. Calculating the number of deaths induced by radiation on whole-life base

The indicator used by UNSCEAR for calculating the radiological risk over the whole of life is the Risk of Exposure-Induced Death, known as REID (or the Life-Time Risk of Exposure-Induced Death, denoted LRED) which is the risk over thewhole of life that an individual will die from a cancer related to a specific exposure. The formula used is the following:

$$REID_c (D, e) = ?_e^8 \,[m_c (a|D, e) - m_c (a)]\, S (a|D, e)\, da \qquad (3)$$

where:

$m_c (a|D, e)$ and $m_c (a)$ are respectively the death rate for the type of cancer c at the age a with and without exposure (D) at age e;

S (a|D, e) is the probability that an individual will still be alive at age a having been exposed to the dose D (and when he/she was still alive) at age e.

The rates mc (a|D, e) are calculated for each type of cancer c using the formulae (1) and (2).

Put simply, the REID indicator expresses the risk over the whole of life that an individual will die of a cancer caused by the exposure to ionising radiation.

Calculation of the risk for a population

The indicators obtained from the exposure-risk relationships are used to determine, notably as a function of sex and age of the individuals and the levels of exposure, the individual probabilities of dying of cancer and how these deaths are distributed in the different years following the exposure.

In examining the risk to a population for a given exposure, it is necessary to take into account the individual probabilities of death and, for each age category considered, the number of people in the population at the time of the exposure.

Put simply, the risk associated with a given exposure for a population can be obtained using the following formula by summing over all the age categories (a) in the population:

$$\sum p_a \,.\, n_a$$

where: p_a is the probability of radiation-induced death for an individual in age category a for a given dose

n_a is the number of individuals in the population in the age category a.

The values of p_a are calculated by summing, for an age category a, the REIDc associated with each type of cancer c (3).

By applying this risk to the entire population, the risk for a statistical individual in the population is obtained:

$$\sum p_a \,.\, n_a$$

? ? ? ? ? ? ? ? ? ? ? ? ? ?

$$\sum n_a$$

Additional deaths due to cancer attributable to a given cumulative exposure

Using the exposure-risk relationship, it is possible to calculate the risk of death due to cancer (leukaemia and other cancers) attributable to a cumulative occupational exposure of 400 man-mSv, for example, by taking into account the age at exposure and the duration of the exposure. Table 1 shows the results obtained by applying the UNSCEAR exposure-risk relationship to a demographic model (the ASQRAD model for calculating radiological risk).

Table 1. Additional deaths from cancer attributable to a given cumulative exposure according to age when the exposure began.

Age at start of occupational exposure	Duration of exposure (years)	Annual dose (mSv/yr)	Additional deaths for every 10,000 men	Additional deaths per year.mSv (10^{-5})
20 years	20	20	258	6.5
20 years	40	10	201	5
40 years	20	20	150	3.7

Although the individual risk does vary, it is reasonable for the purposes of risk management to assume that this variation is not very great. However the ICRP does take these variations into account in order to distinguish between the health detriment of the population of workers from that of the population at large, insofar as the age categories concerned differ substantially in these two kinds of population.

The ICRP health detriment

The exposure-risk relationship used by the ICRP serves to determine the following health detriment for a reference population covering all ages on the basis of a collective exposure. To this end the ICRP introduces weighting factors to allow for the loss of life expectancy, non-fatal effects and hereditary effects. Table 1 shows the nominal probability coefficients for the stochastic effects published in ICRP Publication 60.

Table 2. Nominal probability coefficients for the stochastic effects and health detriment (10-2 Sv-1)

Population Exposed	**Fatal cancers**	**Non-fatal cancers (weighted)**	**Hereditary effect (weighted)**	**Total**
Workers	4.0	0.8	0.8	5.6
Population at large	5.0	1.0	1.3	7.3

1.3. Evaluation of the numbers exposed and the levels of exposure

In the case of exposure to ionising radiation, different types of exposure have to be considered: that due to external irradiation, exposure by inhalation or ingestion, and contamination of the skin. The doses resulting from these various types of exposure can be lumped together into a single indicator that cannot be measured directly: the so-called "effective" dose. In view of the existence of annual dose limits, effective doses are usually calculated over a year.

1.3.1. Occupational exposure

In the case of occupational exposure, it is simple to measure the dose received from external irradiation by means of a dosimeter. External dose can be measured over different periods of time and them integrated with no particular difficulty. As regards contamination of the skin, this essentially arises in incidents in nuclear installations and is therefore not dealt with here. Similarly, exposure due to ingestion is not significant in most occupational exposures.

On the other hand, evaluating the exposure due to inhalation may prove to be more complex in that it requires the dose received to reconstituted on the basis of biological analyses or even from individual air sampling systems that simulate the respiration rate of the people exposed.

1.3.2. Exposure of the public

In the case of exposure of the public resulting from discharges into the environment, because exposure levels are low and there are various possible exposure processes (external irradiation, inhalation or ingestion), the doses are determined by modelling the transfer of radioisotopes into the environment, and the exposure processes. Although the models developed for determining exposures are usually well validated, the central issue is how to define the characteristics of the reference group in order to calculate exposure. After all the reference group may differ considerably according to the purpose in hand (calculating maximum individual dose, the average individual dose around an installation, the average individual dose in a region, and so on).

Since the exposure-risk relationship is linear with no threshold, individual exposures within a population (of workers or members of the public) can be expressed in terms of collective dose (man-Sv), whereupon an expected health detriment can be calculated for the whole of the exposed population. It may be noted that the uncertainties in the calculation increase at lower doses. Accordingly the results of the calculation of collective health detriment must be interpreted with care.

1.4. Optimising radiation protection

Once it is accepted that the exposure-risk relationship is linear with no threshold, it is no longer possible to conceive of radiation protection on the basis of zero risk, for this can only be achieved by reducing the exposure to zero, which in many situations would often involve investing enormous sums of money that could be better used in other aspects of radiation protection.

For this reason the ICRP recommendations for the implementation of radiation protection have been devised on the principle of liability in order to lead to an equitable distribution of risk, better allocation of radiation protection resources and the control of transfers of risk. Accordingly the "As Low As Reasonably Achievable" (ALARA) approach was introduced with the aim of reducing exposures to the lowest level that is reasonably achievable having regard to economic and social considerations. This approach is also known as "optimising radiation protection". The optimisation approach is based upon anticipation and estimation, and involves the following four stages:

- identifying protection options:
- quantifying the effectiveness and costs of options (at this stage, a number of evaluation tools can be used to model exposures and define the expected benefits in terms of reduced exposures - individual and collective - under the different protection options), and qualitatively evaluating the effects of these options in other, sometimes essential fields, such as the availability and safety of the installation,
- comparing and selecting options (this stage sometimes involves analyses of the cost-benefit type and therefore necessitates placing a money value on the health effects that are potentially avoided - the money value of the man-Sievert),
- sensitivity analysis to assist decision-makers better to understand the importance of the uncertainties that are inherent in the evaluation.

This entire approach is based upon the existence of transactions between all those concerned by exposure to ionising radiation: governments, enterprises, workers, elected representatives, and local associations, enabling them to agree on the level of residual risk that workers and members of the public are prepared to accept as a counterpart to the benefits of operating nuclear installations. It may be noted that the money values of the man-Sievert used in applying this approach in professional circles usually take into account not only the money value of the detriment but also the distribution of levels of risk, thus attributing increasing values as a function of the level of individual exposure.

2. APPLICATION OF THE APPROACH TO ASBESTOS AND NICKEL

2.1. Stage 1: Identifying the carcinogenic character

In both cases the carcinogenic character has been unambiguously established for many years [7].

2.1.1. Asbestos

The term "asbestos" covers a variety of hydrated silicates that are formed naturally in the metamorphism of rocks. There are two types of asbestos: serpentine (chrysotile) and the amphiboles (5 distinct species of which the commonest are amosite and crocidolite).

2.1.1.1. Epidemiological observations

The first report that suggested a link between occupational exposure to asbestos and the risk of lung cancer was published by Lynch in 1935. Between 1954 and 1964, 3 group studies confirmed a high incidence of lung cancer in chrysotile miners in Quebec (Braun), in a textile asbestos plant in Pennsylvania (Mancuso) and in an asbestos cement factory in Wales (Elwood).

The epidemiological proof of the link between exposure to asbestos in the Rochdale textile plant (United Kingdom) and lung cancer was rigorously established by Richard Doll in 1955. His conclusions were confirmed by the group study of laggers in the city of New York (Selikoff, 1960).

McDonald et al considered in 1986 that 7% of human lung cancers could be attributed to occupational exposure to asbestos.

As regards mesothelioma, the beginnings of proof were provided by Wagner in 1960 in respect of asbestos miners in South Africa, and these observations were soon confirmed by epidemiological surveys in factories in the United Kingdom, Canada and the United States. In the years that followed similar observations were made in the United Kingdom and Canada on workers producing filters for gas masks and in the United States in factories making cigarette filters.

The International Agency for Research into Cancer (IARC Monograph n° 14, 1977) decided in 1977 that asbestos was carcinogenic to man (lung cancer and mesothelioma).

The death rate due to mesothelioma in man has risen by 5 to 10% a year since 1950, according to data from the United States, Canada, the United Kingdom and Scandinavia. It appears clear that this rise is due to occupational exposure over the last 40 years in the industrialised countries.

2.1.1.2. Animal studies

2.1.1.2.1. Additional risk observed

Experimental work has been done mainly on rats and, to a lesser extent, on hamsters and mice. The animals were exposed by inhalation, intertracheal instillation or inoculation in the pleural or peritoneal cavity. All in all the results of the experimental studies showed that the different types of asbestos produced tumours in rats whatever the method of exposure. As concerns inhalation, the incidence of pulmonary tumours was higher than that of mesothelioma (see table 3).

Table 3. Rates of formation of pulmonary tumours and mesothelioma in rats exposed by inhalation to asbestos fibres

Type of fibres	Type of rat[a]	Concentration[b] (mg/m^3)	No. of rats	Pulmonary tumours	Mesotheliomas	References
Chrysotile	W	10	21	10	1	Wagner et al, 1974
Chrysotile	W	15	45	9	0	Le Bouffant et al 1984-1987
Amosite	W	10	21	13	0	Wagner et al, 1974
Amosite	W	10	40	11	3	Davis et al, 1986
Crocidolite	W	10	18	13	0	Wagner et al, 1974
Crocidolite	OM	7	60	2	1	Smith et al, 1987

a: W: Wistar, OM: Osborne Mendel
b: the exposure time was 24 months or 12 months according to author

2.1.1.2.2. Dose-effect relationship

As regards the dose-effect relationship, the incidence of tumours falls with the dose of fibres inoculated or administered in the form of aerosols. Davis et al (1991) showed that after interperitoneal inoculation of different types of fibres into rats, the relative risk of death due to peritoneal mesothelioma was linear over a dose range from 0.005 mg to 25 mg. There is a practical threshold below which the relative additional risk is zero because the latency time increases as the dose diminishes. Below a certain dose, the latency time exceeds the remaining life of the animal.

2.1.1.2.3. Characteristics of fibres affecting experimental response

As regards inhalation, using a given type of fibre, long fibres are carcinogenic while short fibres are less so or not at all. The dimensional parameter plays a very important role in the carcinogenic nature of the fibres (Oehlert 1991). This is apparently the result of 2 causes: the cytotoxic and genotoxic potential of long fibres (see below) and the fact that short fibres are cleaner than long fibres (Bellman et al, 1994).

The role of the surface properties of the fibres, the persistence in the organism[31] and the influence of the production of oxygen-derived reactive molecular species, remain to be determined.

2.1.1.3 Cellular effects of asbestos fibres

2.1.1.3.1. Mutagenic effects and damage to DNA

In vitro research has shown that asbestos fibres had a slight or zero mutagenic effect as regards the formation of genetic mutations (Reiss et al 1982, Oshimura et al 1984, Hei et al 1992, and others). However chromosome mutations have been observed, demonstrating that the fibres could adversely affect the cell genome by leading to erasures (Hei et al 1992, Both et al 1994). The mutagenesis caused by asbestos apparently results from the formation of molecules derived from oxygen, as indicated by the protection given by anti-oxidising agents (Hei et al 1995).

2.1.1.3.2. Promoter effect

It is recalled that in the initiator effect, an event leading to a mutation causes an irreversible change in the cell genome, while the promoter effect allows a converted phenotype to be expressed, so long as an initiating agent has been previously applied. A number of studies of cultured cells show that asbestos fibres have properties comparable with those of promoters (Marsh and Mossmen, 1991).

2.1.1.3.3. Initiator effect

The work of Lu et al (1988) on mouse fibroblasts, and that of Mikalsen et al (1988), suggest that asbestos fibres have an initiator effect.

The above results tend to show that asbestos fibres are a comprehensive carcinogen, meaning that alone they can cause the transformations necessary for the neoplasmic transformation of cells.

2.1.2. Nickel

2.1.2.1. Epidemiological observations

Historically, the first deaths from lung cancer amongst workers in the nickel industry were observed in the 1930s. The increased incidence of cancer of the lung and nose in workers at the INCO refinery in Clydach, opened in 1902, were recognised in 1933 (Bridge, 1933), workers then being mainly exposed to very high concentrations of oxides of copper and nickel and to soluble compounds of nickel (sulphates), a situation that persisted until the end of the 1930s.

In 1966, the American Conference of Governmental Industrial Hygienists (ACGIH) mentioned a high incidence of fatal cancers (lung and nose) observed amongst workers in refineries in Norway, Wales and Canada, although no specific carcinogen was clearly identified. In 1976, the ACGIH stressed that a higher than normal incidence of cancer was still being observed in workers who had been exposed to nickel sulphide prior to 1960.

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[31] Persistence of fibres in tissue over time.

A review of epidemiological studies on the carcinogenic potential of nickel in man was carried out in 1990 and published in the ICNCM (International Committee on Nickel Carcinogenesis in Man) report chaired by Richard Doll [8].

2.1.2.2. Animal studies

It is reasonable to conclude that the carcinogenic effects of nickel and its compounds were recognised in the 1960s, from the results of a number of experiments on animals. Initial results given in 1958 (Hueper 1958) revealed the appearance of adenocarcinomas in guinea pigs that had inhaled nickel powder, tumours in the lungs being observed later for the same compound (Pott et al. 1987). By 1959 (Sunderman et al. 1959), lung cancers had been observed in rats following exposure to nickel carbonyl. The carcinogenic nature of nickel sulphides by inhalation – malignant tumours – was demonstrated on rats in 1974 (Ottolenghi 1974); that of the oxides, both black and green, in 1975 on hamsters (Wehner et al. 1975) and in 1985 on rats (Horie et al. 1985) – adenocarcinomas and other pulmonary lesions. In 1976 the IARC published a review of the results of animal experiments covering different types of exposure to nickel and nickel compounds (IARC monographs n° 11, 1976).

2.1.2.3. Influence of different nickel compounds on carcinogenesis

There is today a general consensus about the carcinogenic risk to man of certain nickel compounds (classified in group 1 by the IARC as carcinogenic to man)[32] [9], as indicated in the 1990 publication of the ICNCM. The main conclusions of the ICNCM work are given here:

> "…it appears that more than one form of nickel gives rise to lung and nasal cancer. Although much of the respiratory cancer risk seen among the nickel refinery workers could be attributed to exposure to a mixture of oxidic and sulphidic nickel at very high concentrations, exposure to large concentrations of oxidic nickel in the absence of sulphidic nickel was also associated with increased lung and nasal cancer risks.
>
> There was no evidence that metallic nickel was associated with increased lung and nasal cancer risks, and no substantial evidence was obtained to suggest that occupational exposure to nickel or any of its compounds was likely to produce cancers elsewhere than in the lung or nose…
>
> Although the investigation did not provide dose specific estimates of risks for individual nickel species, it is possible to comment on the cancer risks associated with the level of airborne nickel to which the general population is exposed. The evidence from this study suggests that respiratory cancer risks are primarily related to exposure to soluble nickel at concentrations in excess of 1 mg (Ni) /m^3 and to exposure to less soluble forms at concentrations greater than 10 mg (Ni) /m^3. With excess risks being confined to these high levels of exposure and the absence of any evidence of hazard from metallic nickel, it can be concluded that the risk to the general population from exposure to the extremely small concentrations (less than 1 µg (Ni) /m^3) to which it is exposed in the ambient air is minute, if indeed there is any risk at all…"

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[32] As regards nickel metal, the IARC classifies it in group 2B as a substance that is potentially carcinogenic to man, based upon the results of animal studies of this substance.

2.2. Stage 2: Determining the dose-effect or exposure-risk relationship

2.2.1. Asbestos

For asbestos, exposure-risk relationships have been established on the basis of epidemiological studies made on groups of workers.

2.2.1.1. Deaths due to lung cancer

a) Model relating cumulative exposure over time to the additional relative risk of death due to lung cancer.

A relationship between exposure and the additional deaths due to lung cancer was worked out by various authors from 1986 on. This relationship is based upon 11 group studies that give sufficiently detailed and reliable data on occupational exposure to permit investigation of the relationship between cumulative exposure to asbestos and death due to lung cancer. The relationship between the cumulative exposure EC and the relative risk of death due to lung cancer is extremely close to a linear no-threshold relationship:

RRp (cases observed/cases expected) = 1 +Kp x EC

Where: EC = Σ f x d, the sum of the products of the levels of exposure f (expressed in fibres/ml) encountered during working life and the periods d (expressed in years) during which these exposures took place.

Kp is the slope of the linear no-threshold relationship.

The value of Kp is the result of fitting data from the different studies. For the purpose of risk management, the INSERM collective expertise group chose the value of 0.01 in 1996.

The range over which the relationship is valid will be indicated later.

It can be deduced that the additional relative risk of death due to lung cancer ERRp attributable to asbestos is:

ERRp = (0.01 x EC)

b) Model relating cumulative exposure to the additional deaths due to lung cancer over the whole of life in a population.

The additional deaths due to lung cancer Ep attributable to exposure to asbestos is a linear function of cumulative exposure with no threshold. It is equal to (0,01 x EC) x cases expected. It depends on the number of cases expected and hence on the age of the persons exposed. It is therefore appropriate to calculate the additional deaths due to lung cancer over the whole of life attributable to exposure to asbestos. This calculation employs a method very similar to that used for calculating the additional "whole life" risk attributable to ionising radiation (see panel in section 1.2)

To sum up, the number of additional "whole life" deaths due to lung cancer resulting from occupational exposure between the ages of 20 and 65 to 0.1 fibres/ml of chrysotile asbestos is, according to the previous relationship applied to a group of 10,000 French workers, equal to 21.5 (or 0.21%). These deaths are in addition to the 520 deaths expected in any group of 10,000 people representative of the French male population (notably as a result of its tobacco habit) not occupationally exposed to asbestos.

It may be noted that the additional "whole life" risk varies slightly with the duration of exposure and depends essentially on the cumulative exposure EC. For example, for a given cumulative exposure of 200 years.fibres/ml as from the age of 20, the number of excess lung cancers in a population of 10,000 men exposed for 20 years to 10 f/ml or for 40 years to 5 f/ml will be 1041 and 992 respectively.

2.2.1.2 Deaths due to mesothelioma

a) Model linking the concentration of fibres in air to the excess mortality rate due to mesothelioma.

The exposure-risk relationship is based upon the multi-stage model of carcinogenesis proposed by Armitage and Doll in 1961. The initial forms of the relationship stem from the research of Newhouse and Berry in 1976 which were taken up by Doll and Peto in 1985.

The excess mortality rate due to mesothelioma attributable to exposure to asbestos Em (t) is:

Em (t) = Km x f x [(t-10)3 - (t-10-d)3], for an exposure that ended[33] in the last 10 or more years (t-d >10),

where:

Km: constant that may depend on the group studied,

d: duration of the exposure in years,

f: mean level of concentration expressed in f/ml during the period d,

t: number of years elapsed since the start of exposure,

the value 10 denotes the minimum time period (time shift) for the risk of mesothelioma to appear.

Em is an absolute estimate of the excess number of deaths due to mesothelioma and not a relative estimate, as it is in the case of lung cancer. The relationship is found to be linear, with no threshold, as a function of f, the mean level of concentration during a period of exposure.

The value of Km is the result of fitting the data from the different studies. For the purposes of risk management, the INSERM collective expertise group chose the following values in 1996:

10^{-8} for exposure to chrysotile alone,
$3.\ 10^{-8}$ for exposure to amosite alone,
$1.5.\ 10^{-8}$ for exposure to the chrysotile-amosite mixture.

The range over which the relationship is valid will be specified later.

b) Model relating cumulative exposure to the additional number of deaths due to mesothelioma over the whole of life in a population.

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[33] If the exposure is current or ended within the last 10 years, the expression becomes Eim (t) = Km x f x [(t-10)3]

To sum up, the number of additional "whole of life" deaths due to mesothelioma resulting from occupational exposure between the ages of 20 and 65 to 0.1 f/ml of chrysotile asbestos is, according to the previous relationship applied to a group of 10,000 French workers, equal to 10 (or 0.1%). These deaths are in addition to the 0.5 to 1 deaths due to mesothelioma expected in a group of 10,000 persons representative of the French male population who are not exposed occupationally to asbestos.

The additional number of deaths due to mesothelioma over the whole of life attributable to exposure to asbestos is also calculated using the method set out in the panel in section 1.2.

It may be noted that the additional number of deaths due to mesothelioma over the whole of life varies significantly with the duration of the exposure, for a given cumulative exposure value. For example, for a cumulative exposure of 200 years/fibres/ml, as from the age of 20, the number of deaths due to mesothelioma in a population of 10,000 men exposed for 20 years to 10 f/ml or for 40 years to 5 f/ml will be 882 and 497 respectively.

2.2.1.3. Additional deaths due to cancer attributable to cumulative exposure to 1 year.fibre/ml of asbestos.

Let us consider the additional risk of death due to all types of cancer (cancer of the lung and mesothelioma) related to a cumulative exposure of 200 fibres/ml for example, in a population of 10,000 men. Depending on how the exposure varies over time, the additional risk will be as follows:

Table 4. **Additional risk of death due to all types of cancer ascribable to exposure to asbestos**

Age at start of exposure	**Duration of exposure**	**Concentration**	**Additional deaths for 10,000 men**	**Additional individual risk of death/ [year/fibre/ml] (10^{-4})**
20 years	20	10	1923	9.6
20 years	40	5	1489	7.4
30 years	20	10	1388	6.9
30 years	30	6.67	1231	6.1

The change in the individual risk of death can be regarded as relatively low for the purposes of risk management, and is of the same order as that found in the case of ionising radiation.

This allows us to conclude that as a first approximation, the additional risk of death over the whole of life ascribable to exposure to asbestos is about 7.10-4 per year.fibre/ml of occupational exposure.

2.2.1.4. Range of validity of exposure-risk relationships

The INSERM collective expertise report provides very important details in this connection [6].

2.2.1.4.1. Broncho-pulmonary cancer

We have seen that the relationship is a linear function of the cumulative exposure over time (expressed as f/ml x year). The levels of asbestos concentration encountered in the groups vary from a few f/ml to a few dozen, with extreme values ranging from 1 f/ml to 250 f/ml. It has not been possible to evaluate the specific effect of the level of concentration, for comparable cumulative exposure, below 1 f/ml. The linear no-threshold dependence on cumulative exposure does not in itself demonstrate the existence of a linear no-threshold effect of the level of concentration.

Also, the cumulative exposure considered in the exposure/risk relationship encompasses situations of continuous exposure (throughout the day, every day of the week, every week of the year). No direct information is provided by the studies used for drawing up the exposure-risk relationship about the risks arising from discontinuous or sporadic exposures.

Accordingly the relationship cannot be applied to these situations, and it is not known whether, for the same cumulative exposure, discontinuous exposure leads to a higher or lower risk than continuous exposure.

2.2.1.4.2. Mesothelioma

The three studies used for formulating the relationship refer to situations of high cumulative exposure (50 f/ml x year to 500 f/ml x year), for which the levels of concentration are also high: 15 f/ml to 35 f/ml/

Moreover, as for broncho-pulmonary cancer, the exposures dealt with in the studies are continuous. Accordingly the relationship cannot be applied to situations of discontinuous exposure.

2.2.1.5. Extrapolation to low levels of concentration

We have seen that the relationships were worked out on the basis of exposure situations in which the concentration exceeded 1 f/ml for broncho-pulmonary cancer and 15 f/ml for mesothelioma. The joint group of experts decided that for the purposes of risk management it was possible to extend the relationships to the range of concentrations below 1 f/ml. In fact INSERM considered that this linear no-threshold extrapolation to low exposures was “the most plausible uncertain estimate in the present state of knowledge”.

We saw in particular in stage 1 that the investigations of animal carcinogenesis by inoculation showed a linear no-threshold relationship down to low dose levels. Cellular research tends to suggest that the asbestos fibres have a characteristic promoting and initiating effect that is compatible with the no-threshold hypothesis.

The situation is therefore the same as for ionising radiation, since the linear no-threshold relationship was adopted by the ICRP for the purposes of managing radiological hazards.

It will be noted that the exposure-risk relationships worked out for asbestos, although subject to the limitations inherent in the uncertain process of reconstructing exposure, stem from the use of epidemiological surveys of occupationally exposed groups. They imply a shorter “extrapolation length” than the exposure-risk relationship worked out for ionising radiation, based essentially on the results of the epidemiological study of survivors of the Hiroshima and Nagasaki atomic bomb explosions.

2.2.2. Nickel

In the case of environmental exposure to nickel (exposure through inhalation of particles), the difficulty in evaluating the risk linked to this exposure lies in the formulation of a dose-effect relationship that is applicable to the field of exposure in question, as regards both the levels of exposure and the physical and chemical nature of the compounds encountered in the environment. The dose-effect relationship for nickel is drawn up on the basis of the following:

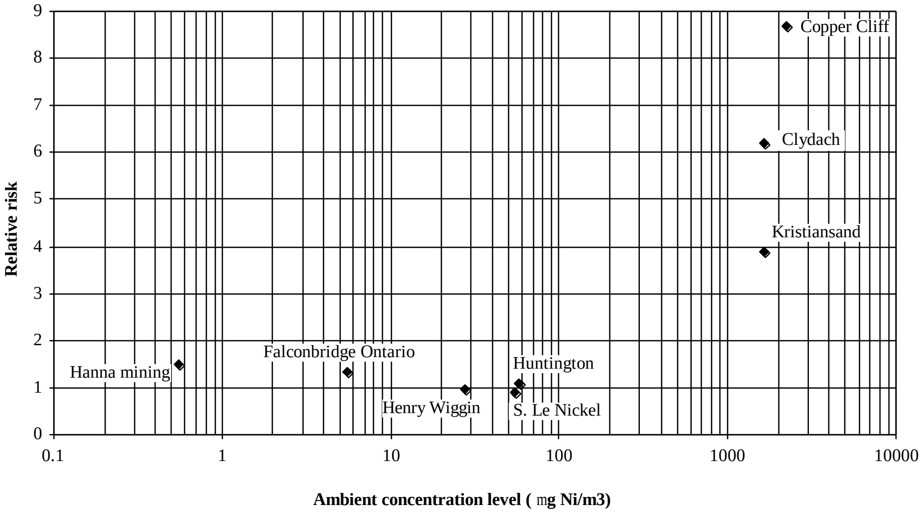
- The results of epidemiological studies conducted on workers in the nickel industry (occupational exposures),
- Extrapolation of this dose-effect relationship to the field of exposure considered (level of concentration and physical and chemical nature of discharges into the environment).

It may be noted that the levels of public exposure (a few tens of ng Ni/m3) are nearly one million times less than the levels of exposure considered in the epidemiological studies covering only occupational exposures (a few mg Ni/m3). Also the chemical forms of the nickel in the surrounding air differ from the chemical forms encountered in occupational environments. The latter stem mainly from soluble nickel and its sub-sulphides; as regards nickel metal there is no evidence of its being carcinogenic to man but there is a causal link in animal studies [IARC]. The initial measurements in the ambient air essentially reveal nickel in the complex form of the sulphate and the oxides. Also cancers of the nose, which are linked to very high exposures, for particles of large size, have been excluded from the quantification of risk at low exposure levels, since no additional risk was found in the epidemiological studies of occupationally exposed groups, once the particles are of smaller size.

2.2.2.1 The models used for the "whole of life" calculation

Ten epidemiological studies have been extrapolated to low doses by different organisations (Figure 1): the Environmental Protection Agency (EPA), the World Health Organisation (WHO) and the Californian Air Resources Board (CARB). It will be seen that there is considerable scatter of the cumulative levels of exposure over the whole of life. Some of these evaluations have been reviewed by NiPERA (nickel producers).

Figure 1. **Relative risk associated with cumulative occupational exposure to nickel and its compounds**



All the extrapolations done using these data are based on a linear no-threshold model. Two types of model were used. These were, first, the additive model in which the additional risk is proportional to the cumulative dose and is added to the basic risk and, secondly, the multiplicative model (or relative risk model) in which the nickel acts as a multiplier of the basic risk. These models are relatively simple and do not take the age at exposure into account. The risk is calculated for an average population of workers.

In the additive model, the additional mortality (by age and cause) is augmented by an amount proportional to the cumulative exposure; the additional risk for a given level of exposure is regarded as constant for different ages. This leads to the following formula for the total risk, or the number of deaths expected in the population exposed:

86 573 602 2772$\vartheta = \vartheta_0 + \vartheta_1 = \vartheta_0 + k.X.W$

where:

ϑ	number of deaths observed during the period having regard to the exposure
ϑ_0	number of deaths expected in general mortality (excluding exposure)
ϑ_1	number of additional deaths having regard to the exposure
k	factor of proportionality
X	mean annual level of exposure (or concentration)
W	number of persons.year exposed

Hence the parameter k can be calculated as follows:

$k = (\vartheta - \vartheta_1) / (X.W)$

In the model of relative or multiplicative risk, the factor investigated is assumed to act as a multiplier on the basic risk. In this case the relative risk RR remains constant with age. In this case the formula becomes:

$\vartheta = \vartheta_0 (1 + k.X)$

The parameter k is then calculated as follows:

$k = [(\vartheta / \vartheta_0) - 1] / X = (SMR - 1) / X$

where:

SMR	standard mortality rate

These two models used for determining the risk at low dose were discussed by the EPA and the CARB, when the multiplicative model was generally considered to be more suitable having regard to the available data for the different groups. The WHO uses a mean relative risk model formulated as follows:

$$UR = \frac{P_0(RR - 1)}{X}$$

where:

UR	additional risk of cancer
P_0	risk of death over the whole of life for the population at large (excluding exposure)
RR	ratio between the cases observed and those expected, having regard to the age and sex structure of the reference population
X	mean exposure (expressed as mean concentration)

The additional risk over the whole of life is a function of the mean exposure. In this formulation, the relative risk is a function of the cumulative exposure (represented here by the mean concentration). This method is easy to apply. However the WHO stresses the difficulty of having to use a mean exposure which is usually calculated as a function of concentration for the different years of exposure and the exposure duration, since the concentration can vary substantially over time.

2.2.2.2. Extrapolation to low doses

Having regard to the different types of extrapolation proposed and in view of the available data, three studies can be used for evaluating risk at low dose. These are the Clydach study (Wales), Copper Cliff (Ontario) and Kristiansand (Norway). The results are given in Table 5.

Table 5. **Additional lung cancers for a lifetime exposure to 1 µg Ni/m ^{3} of a population for 10,000 people – Estimates resulting from extrapolations made by different organisations on three groups that have been the subject of an epidemiological study**

		Group		
Organisation		Clydach	Kristiansand	Copper Cliff
WHO	1987 1995	5.7	5.9 9.6	1.5
CARB	1991			2.57
EPA	1986	0.8 to 4.6	0.19 to 1.9	0.89 to 1.2
NiPERA	1995			0.91

The epidemiological study for Clydach covered the period 1907-1984 (77 years), for a population exposed from 1902 to 1969. The size of the population studied is 2521 workers, of which 1348 were recruited before 1930. The chemical species identified were the metal (from 0.05 to 6 mg (Ni) /m3), the oxide (from 0.1 to 18.75 g (Ni) /m3), the sulphide (from 0.01 to 18 mg (Ni) /m3), and soluble compounds (from 0 to 2 mg (Ni)/m3). The fact that workers moved from one type of workshop to another made it difficult to individualise the types of hazardous substances.

For the Copper Cliff group, the epidemiological study extended from 1950 to 1984 (34 years) for a population of 1754 workers employed between 1914 and 1976. The chemical species identified were the metal, the oxide, the sulphide and soluble compounds.

For Kristiansand, workers were less mobile than at Clydach. The group studied consisted of 3250 workers employed between 1946 and 1969, the period of the study covering the period 1953 to 1984 (31 years). The chemical species identified were the metal, the sulphide, the oxide and soluble compounds. Recently the group was further analysed by Andersen et al as regards the workers employed between 1916 and 1983 (4505 people). The authors concluded that the risk persisted, including for those employed after 1968.

The EPA excluded the extrapolation done in Huntington from the definitive calculation, owing to the small size of the sample and the wide confidence interval, and retained only the three groups mentioned above. The WHO, in its 1995 revision, rejected the results of the Clydach and Copper Cliff groups, but did not give reasons for this in its “Air Quality Guidelines”. Finally, a publication by Anderson et al. in 1996 refers to the problems of the role played by tobacco in the group covered by the Kristiansand study.

2.2.2.3. Extrapolation to the case of environmental exposure

In 1987, the WHO published its "Air Quality Guidelines". In 1993, in co-operation with the European Commission, the International Programme on Chemical Safety (IPCS) was set up. In 1994 a working group (Düsseldorf), which was set up to devise recommendations on how to establish a consensus on "guide" values for air quality and on the estimates of the risk associated with nickel, concluded with an additional risk of lung cancer of about 10^6 per ng/m^3, for a whole of life exposure, making the assumption of a linear no-threshold dose/response relationship.

A recent study (estimate proposed by the CAREPS in the CEPN study) combined these different epidemiological studies (see Table 5), and on the basis of a simple linear extrapolation, suggested an additional risk of lung cancer of 2.5 10-7 for a whole of life exposure to a concentration of 1ng (Ni) / m3[10].

However data obtained from animal experiments make it possible to adjust a number of parameters in the extrapolation of the dose-effect relationship obtained previously, to the field of environmental exposure, essentially as regards the different biological properties of compounds. Thus in the recent study (CEPN) the results derived from animal experiments for the additional risk for a whole of life exposure to 1 µg (Ni) /m3 are 0.4.10-4 for NiO and 3.10-4 for Ni3S2. In fact the chemical forms encountered in the general environment cannot be sub-sulphides of nickel (Ni3S2) and, also, the amount of the oxide NiO cannot exceed 8% in the ambient air. Finally, nickel sulphate is acknowledged to be the main component of the nickel compounds soluble in the ambient air (accounting for about 50% of the compounds of airborne nickel).

Accordingly, by combining the results obtained in animal experiments with those of the epidemiological studies, the risk values extrapolated to the ambient air that take account of these adjustments (physical and chemical form) lead to an additional risk of death due to lung cancer of the order of 10^{-7} for a whole of life exposure to 1ng (Ni) /m^3, expressed in terms of total nickel. Using this whole of life risk for an environmental exposure to nickel, a simple calculation will give an estimate of the annual individual risk (in terms of additional risk of lung cancer) associated with a concentration of 10ng(Ni) /m3, of about 1.4 . 10-8.

With regard to cancers of the nose, the exposure-risk relationships have clearly demonstrated an additional risk for very high levels of exposure and particles of large size. For the other types of exposure, no additional risk has been observed in the epidemiological studies of occupational exposure, which has led the organisations to exclude cancer of the nose from the quantification of the risk at low levels of exposure.

2.3. Stage 3: Exposure indicators

2.3.1. Asbestos

For quantitatively evaluating the additional deaths due to cancer over the whole of life, we have seen that the cumulative individual exposure, expressed in years.f/ml, can be used once the exposure can be regarded as continuous and not sporadic. Cumulative exposure can be determined by measuring the concentration of asbestos fibres in the working atmosphere, so long as these are representative of the annual mean exposure. Clearly it is also necessary to know the number of years of exposure. Employing the assumption of a no-threshold linear relationship between the excess risk of death due to cancer and cumulative exposure, it is possible, as for ionising radiation, to define a collective exposure indicator, expressed in person.years.(f/ml). This indicator provides an evaluation of the additional deaths due to cancer in a population subjected to continuous exposure to asbestos.

2.3.2. Nickel

Adopting the assumption of no-threshold linearity, the exposure-risk relationship was extrapolated to the levels of concentration expected in the ambient air by taking into account certain adjustments that reflect the differences in physical and chemical properties of the different compounds of nickel, based upon the results of animal experiments.With this approach, in the absence of adequate data on the differentiation of the chemical species in the general environment and the specific carcinogenic potential, it is possible to use the total quantity of nickel present in the ambient air to express the level of exposure of the population at large. The exposure indicator adopted then corresponds to the mean concentration of total airborne nickel, once it is considered that the level of concentration is constant over the whole of life.

Put simply, the additional whole of life risk for a statistical individual in the population is obtained by multiplying the risk coefficient by the mean concentration of total airborne nickel, to the extent that the exposure-risk relationship is regarded as linear in the exposure range investigated. This approach has the advantage of giving a risk indicator that is easily calculable from a measurable variable: the concentration of nickel at the exposure location.

In this way it is possible, for a given population, to calculate the whole life risk for levels of concentration that change with time by determining a mean value of concentration. It must be pointed out that since the risk arising from exposure to airborne nickel is low, the change in the survival curve of an individual exposed to nickel in the environment will be no more than marginal. As a result the simplification introduced by using the mean concentration over the whole of life does not introduce any significant error into the calculation of the additional whole of life risk.

From the standpoint of collective risk it is feasible, as in the case of ionising radiation, to determine the collective exposure in a given region. For each zone in which the concentration, expressed as ng Ni / m^3 in the ambient air, is similar, it is possible to determine a collective exposure indicator, as follows:

“number of persons x mean concentration in the zone”

By assuming the population to remain constant over a long period, as a further simplification, the number of additional cases of lung cancer due to exposure to airborne nickel is obtained by multiplying this collective exposure indicator by the coefficient of whole life risk.

2.4. Stage 4: Reducing risk: provisional review of preventive actions

A common underlying assumption used for risk assessment is that there is no threshold of harm. We have seen that for asbestos, as for nickel, it is not possible, on the basis of the many scientific data currently available, to suggest a threshold value of cumulative exposure or concentration below which the additional deaths due to cancer attributable to exposure to asbestos or nickel would be zero.

The no-threshold assumption made in the context of risk management has resulted in the prevention of carcinogenic risks being based upon the search for preventive actions liable to reduce the risk and in adopting those that lead to exposure being reduced to a level “as low as reasonably possible”.

2.4.1. Asbestos

The provisional review of preventive actions is defined here with reference to the type of formal optimisation process introduced in the management of radiation hazards. The provisional review involves evaluating, at the stage of preparing an intervention, the reduction in exposure expected from the introduction of the different preventive actions being envisaged.

The reduction in exposure will be provisionally evaluated from the concentration of asbestos fibres in breathable air. As regards sporadic exposure, the relevant concentration indicator will be the value of the concentration peaks rather than the mean over a certain period. For continuous exposure, the mean concentration will be used, from which it is possible to deduct the cumulative exposure avoided (from knowledge of the duration of exposure) and, consequently, to measure the cancer death risk that has been avoided.

2.4.2. Nickel

We have seen that the risk to the population at large arising from airborne nickel was evaluated using an exposure-risk relationship in which the exposure indicator was expressed as the concentration of total nickel in the air, usually in terms of ng (Ni) / m^3. This concentration value can be obtained either by direct measurement, or by modelling the transport of nickel from an emission point.

Just as for radioactive discharges into the environment, preventive actions related to discharges of nickel into the environment are evaluated on the assumption that it is possible to link the emissions of nickel to the concentration levels found in the ambient air. Theoretically speaking, such an approach is feasible so long as the sources of emission are identified and that there are suitable models for transfers into the environment. Then, using the exposure indicator adopted, it is possible to work out the expected effects of reducing nickel emissions into the environment (and hence the concentration in the ambient air).

However even at this stage there are two difficulties in applying this approach: the models for conducting these calculations are not yet available (in particular the way in which nickel is transferred into the environment is not accurately known) and the sources of emission are still not completely understood. There is a major difference from the case of radioactive discharges into the environment: nickel emission sources are very diverse, which means that modelling the connection between emissions and concentrations in the ambient air is extremely complex.

2.5. Stage 5: Comparing preventive actions - choices

2.5.1. Asbestos

Preventive actions can be compared by looking at their costs and the reduction in concentrations of asbestos fibres they bring about. The choice between the different actions can be guided by a "cost-effectiveness" analysis leading to a ranking of the actions according to the "cost of the year.fibre/ml avoided".

It will in principle be possible, just as for ionising radiation, to define a reference money value analogous to the money value of the man.Sievert. It will be recalled that the man.Sievert quantifies the risk of death due to radiation-induced cancer, and that it is then possible to deduce a money value of the man.Sievert from the "cost of deaths avoided". In the case of continuous exposure to asbestos, the equivalent of the man.Sievert is the man.year.fibre/ml.

In the case of continuous exposure to asbestos, the choice between preventive actions could in principle involve a formal optimisation procedure comparable to that used for ionising radiation.

2.5.2. Nickel

Apart from the difficulties inherent in applying the optimisation approach for radioactive discharges into the environment (notably as regards the field of application of the collective exposure indicator: where does one stop in the space-time integration?), the different protective actions to reduce exposure to nickel in the environment could be compared on the basis of the ALARA approach.

Consideration could be given to an initial approach in terms of public health, involving determining the number of lung cancers avoided under the different protection options envisaged for reducing sources of emission. In fact since the risk associated with airborne nickel is here limited to inhalation, only those protection options that involve reducing nickel emissions at the source are to be considered.

Later on consideration can be given to analyses of the cost-effectiveness or even cost-benefit type (by attributing a money value to each cancer avoided) in order to compare and select the protection options

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ANNEX II

REGULATORY PROVISIONS[34]

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[34] Only certain aspects of regulations relating to the primary prevention of risks associated with ionising radiation, asbestos and nickel in France (or perhaps at European level) will be considered here.

1. IONISING RADIATION

The dose limitation system recommended by the ICRP involves setting a dose limit and achieving "ALARA" levels below that level. This system has been taken up into European regulations and then into national regulatory systems, following ICRP publication 26 in 1977, and then publication 60 in 1990 (as concerns this latter publication, preparations are in hand to transpose it into French regulations on the basis of European directive 96/29 of May 1996).

1.1. Exposure limits: status and trends

1.1.1. Occupational exposure

Current French regulations, which are based upon ICRP publication 26, set individual dose limits at 50 mSv/year and at 30 mSv per quarter. The ICRP justifies the level of 50mSv/year with reference to the level of occupational risk the industrial countries regarded as implicitly "acceptable" during the 1970s. Values of risk are converted to dose using the exposure-risk relationship. The recommendations of publication 60, which underlie the new European dose limit and which will be adopted in France in May 2000 at the latest, are based upon a number of considerations – not always explicit – for justifying the new value (100 mSv over 5 years without exceeding 50mSv/year). These considerations include:

- a redetermination of the risk of organ cancer (i.e., excluding leukaemia) per unit of dose following the adoption of a model based on relative risk rather than absolute risk (with a risk coefficient changing from 1.25. 10^{-2} deaths due to cancer/Sv to 4. 10^{-2} deaths due to cancer/Sv).

- the implicit acceptability of the technical and economic applicability of the new limiting value since the change in model should have resulted in the adoption of an individual dose limit of about 15 mSv/year, or even less, to take into account the progress made between 1977 and 1990 in "conventional" industry regarded as "safe" that had served as a reference in ICRP publication 26.

These considerations remain implicit because the dose limitation system is formally based upon a 2-stage process[35]:

- a differentiation between the "unacceptable" level of risk and the "tolerable" level which is assumed to encompass only considerations related to individual health risks,

- the consideration of economic and social factors to determine the "acceptable" dose level which is then the "ALARA" level.

1.1.2. Exposure of the public

The current regulatory dose limit for the public is 5 mSv/year. When the European directive of May 1996 is transposed into the French system, this limit will be lowered to 1 mSv/year. The value of 5 mSv/year was essentially based upon considerations of risk acceptability (the acceptable mean annual

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[35] We do not discuss here the justification principle which is only remotely linked to our subject

individual risk[36] acceptable (in terms of deaths) being set between 10-6 and 10-5 in ICRP publication 26). To justify the new limit of 1 mSv/year, the ICRP (publication 60) takes account of the associated residual risk, but also invokes considerations of changes in the level of natural irradiation.

1.2. Monitoring exposure

1.2.1. Occupational exposure

French regulations provide for two complementary types of external dosimetry to coexist. The older – film dosimetry – indicates the monthly (or quarterly) dose and hence the annual dose received by workers. Data from this dosimetry system are recorded in a central system managed either by the French Office de Protection contre les Rayonnements Ionisants, or by enterprises themselves, in the case of large industrial firms and nuclear research undertakings. Since March 1999, so-called "operational" dosimetry has been recognised as regulatory. In particular this development reflects the need to have regulatory facilities for ensuring that the optimisation principle is applied.

The arrangements currently in force provide for a prior evaluation of collective and individual doses and for measurement of doses actually received occupationally. Individual data from operational dosimetry are sent periodically to the OPRI for statistical or epidemiological purposes. Access to individual data resulting from operational dosimetry is reserved to those said to be "skilled in radiation protection" or "qualified" persons. Practical rules for data transmission make OPRI responsible for centralising the results, notifying the employer if dose limits are exceeded and processing and utilising the results.

In principle, therefore the regulations provide for the implementation of the means necessary for identifying exposed persons and the levels of external exposure for each individual and post.

Surveillance of internal exposure is one of the tasks of occupational medicine. It is based upon body gamma measurements and radiotoxicology examinations.

1.2.2. Exposure of the public

Hitherto the doses received by the public have been quantitatively estimated when the operator has submitted a request for discharge permit. The request has to show in particular that the persons in the reference groups (i.e., those who are most exposed) receive a relatively low dose which is in any event less than the dose limit for members of the public. Thus a link is established between the discharges from the installation and the mean individual dose received by those in the reference groups. It will be noted that in this context only the individual dose is of importance, and the collective dose received by members of the public located at varying distances from the installation is not taken into account.

In 1999 the regulations governing discharges should make it compulsory for the operator to draw up an annual report containing an estimate - as realistic as possible - of the doses received by the reference groups as a result of the activities during the previous year. Here again, and in line with the requirement at the stage of the provisional study, only the doses to the most exposed individuals are required and not the collective dose impact of the installations.

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[36] According to the ICRP, the dose limit of 5 mS/year is equivalent on the average to a mean individual dose of 0.5 mSv/year, hence a risk of the order of 0.6.10-5, using the relationship of 1.25.10-5 per mSv, which was used at the time of ICRP publication 26.

1.3. The optimisation principle

1.3.1. Occupational exposure

Current French regulations provide for the implementation of the optimisation principle as regards occupational exposure (Decree 75-306 of 28th April 1975 modified by Decree 88-662 of 6th May 1988): "Equipment, processes and the organisation of work should be designed in such a way as to keep individual and collective occupational exposures as low as reasonably possible below the limits prescribed by the present Decree. For this purpose, jobs incurring exposure are the subject of a review at intervals determined by the level of exposure".

1.3.2. Exposure of the public

In France as in many other countries, discharges from nuclear fuel cycle installations (which make up most of the "basic nuclear installations") are limited by requiring the operator to submit a request for a discharge permit. The request documents should enable the public authorities to fix the amounts of radioactivity authorised and the technical conditions governing the discharge of liquid and gaseous effluent in the context of the normal operation of an installation. It is to be noted that it is the discharges and not the doses that must be "kept as low as reasonably possible", on the basis of the use of the "best available technologies at economically acceptable cost and the particular features of the site environment". In practice, as we have already pointed out, a prediction of the doses liable to be received by the reference groups is also included in the application.

Finally we will recall that European directive 96/29 on the basic standards, now in the process of being transposed, requires that "all exposure be kept at the lowest level reasonably possible, having regard to economic and social factors".

2. ASBESTOS

2.1. Exposure limits: status and trends

The limitation of occupational exposure is based upon exposure limits that must not be exceeded. In France, as in other countries, the limiting values have been progressively lowered. The first value was 2 f/ml set out in the Decree of 17th August 1977. Next, the Decree of 27th March 1987 was issued to bring the country into line with the European directive of 19th September 1983. This set the limiting values at 1 f/ml for varieties of asbestos other than crocidolite, 0.8 f/ml for mixtures and 0.5 f/ml for crocidolite. The Decree of 6th July 1992 further lowered the values in compliance with the European directive of 25th June 1991: 0.6 f/ml when chrysotile is the only type of asbestos used, and 0.3 f/ml for all other varieties. The European directive of 25th June 1991 is still in force, but France, like other countries, decided to lower the exposure limits by adopting Decree 96-98 of 7th February 1996 which provides for 0.3 f/ml over 8 hours of work for chrysotile and 0.1 f/ml as from 1/1/98.

Decree 96-98 of 7th February 1996 modified concerning the protection of workers against the risks arising from the inhalation of asbestos dust stipulates that the mean concentration of asbestos fibres in the air inhaled by a worker should not exceed 0.1 f/ml over 8 hours of work in the case of chrysotile and 0.1 f/ml over 1 hour of work when other types of asbestos are also present.

It may be noted that this value was justified, in discussions in the expert committees, as being that corresponding to the lowest cumulative exposure leading to a statistically significant additional risk[37] in one of the epidemiological studies used as a basis for quantifying the risk. This is therefore a "lowest observed effect level".

Hence this exposure limit is a "hybrid" in that it satisfies a number of concerns:

1) reducing the residual risk, without eliminating it, since the exposure limit encompasses an additional risk.

2) adopting a value that has operational meaning, in that it is measurable. It appears that 0.1 f/ml is the practical sensitivity threshold of the instruments used professionally.

The Decree of 7th February 1996 modified marks a more general trend in how the prevention of occupational risk arising from asbestos is perceived, and it rescinds the Decree of 17th August 1977 and its subsequent modifications. The new Decree brings in a very clear distinction between three types of activity:

- the production and manufacture of materials containing asbestos,
- the containment[38] and removal of asbestos,
- working with or on materials or systems liable to release asbestos fibres.

By making such a distinction, the public authorities acknowledge the need to deal separately with these three situations, particularly those of the third type, for which article 27 specifies that these are activities "the objective of which is not to process asbestos but which are liable to lead to the emission of asbestos fibres". This type of heterogeneous activity could be said to have been implicitly "forgotten" in the successive versions of the earlier Decrees which stipulated that they were applicable notably to industrial, commercial and agricultural establishments "for those parts of premises and sites where personnel are exposed to the inhalation of asbestos dust in the free state in the atmosphere".

These old provisions reflected the contemporary idea, strongly promoted by the asbestos industry lobby, that "controlled use" of asbestos was possible and that there was therefore no need to envisage measures as radical as prohibiting the manufacture and use of asbestos.

However by the Decree of 24th December 1996 it was decided to ban asbestos in France, with a few provisional exceptions for certain purposes for which no substitute could reasonably be envisaged in the short term. Besides the concern for taking vigorous action in view of public opinion that was highly sensitised to what had become the "scandal" of asbestos, the public authorities probably took two other considerations into account:

- the fantastic growth in the uses of asbestos during previous decades generating a risk of cancer:
- the population at large being exposed to a "passive" risk in dwellings where the atmosphere might be contaminated by asbestos released from flocking, lagging and false ceilings,
- the population at large as a result of DIY activities,

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[37] 5 (fibres/ml).years, or 0.1 f/ml over a period of 50 years

[38] it is a question of preventing fibres from being released into buildings, for example by « encapsulating » the materials concerned.

- workers using materials or systems liable to release asbestos fibres.
- continuing the manufacture and use of asbestos would be tantamount to sustaining an uncontrollable source of danger in the future, whereas through a tardy dawn of awareness, the public authorities realised how the utopia of the controlled use of asbestos had led them into a dead end.

The reasons for reducing exposure limits

The precise reasons for the continued reduction in asbestos exposure limits remain to be determined. A few remarks may be apposite here. First of all, the exposure-risk relationships, which have existed since 1986, as we have seen, have not been utilised in the debate about the additional residual risk associated with the limiting values. The exposure limit has been and remains conceived as a value not to be exceeded, but it does not appear to have been regarded as a threshold of harm. The European directive of 1983 already set the exposure limits at 0.8 f/ml or at lower values and these values have been lowered continuously since.

2.2. Monitoring exposure

Decree 96-97 of 7th February 1996 concerning protecting the public against the health risks arising from exposure to asbestos in dwellings is aimed at identifying, recognising, displaying and proving the presence of asbestos in dwellings and workplaces. This refers to office premises in which people may suffer passive exposure to asbestos.

We may point out this Decree is the first legislation that makes compulsory the identification of persons exposed to asbestos. As regards the exposure of workers, nothing of this kind existed until February 1996. Since the promulgation of Decree 96-98, issued on the same day, 7th February, concerning the protection of workers, there are the following provisions:

- for workers involved in the production and manufacture of materials containing asbestos, establishment heads must specify in particular the number of workers exposed, and the nature, duration and level of the exposure. This provision lapses with the Decree of prohibition,
- for workers involved with materials or systems liable to release asbestos fibres into the buildings coming under the inventory provided for in Decree 96-97, the heads of enterprises must obtain from the owners of buildings the results of the searches and tests carried out during the inventory.

2.3. The control of asbestos and the optimisation principle

In France, there is no reference to the search for levels “as low as reasonably possible” with regard to occupationally carcinogenic substances (other than ionising radiation). However there are provisions relative to carcinogenic substances (article R 231-56-3 of the Employment Code) which stipulate that “if it is impossible to apply a closed system, the employer shall ensure that the level of exposure of workers is reduced to a level as low as technically possible”.

In the case of asbestos, it is reasonable to consider that the limiting values now in force in France constitute an objective that is very difficult to achieve and that the issue is not, as in the case of ionising radiation, to reduce exposures below the exposure limits.With regard to the production and manufacturing of materials containing asbestos, prohibited since the beginning of 1997, the Decree clearly states that “the inhalation of asbestos dust must be reduced to a level as low as technically possible" … and that in any event the mean concentration must not exceed the exposure limits. For the tasks of containing and removing asbestos, and activities involving materials liable to emit asbestos fibres, achieving the exposure limits is certainly a challenge and means that the use of individual protection systems (wearing filter masks or ventilated suits) is essential.

The Order of 14th May 1996 concerning the technical rules to be followed by enterprises involved in containing and removing asbestos introduced very precise provisions, particularly as regards the containment of worksites, and the collective and individual protective systems. The following are a few examples: "Construction of a containment impermeable to air and water around construction components, structures, … A tunnel comprising five compartments (airlock) enabling the decontamination of workers and equipment should represent the only access for people from the exterior into the working area".

"The working area shall be kept at a negative pressure with respect to the exterior by the introduction of suitable extractors, fitted withprefilters and absolute filters of very highefficiency …" – "All persons inside the working area shall be continuously equipped … with isolating breathing apparatus with a compressed air inlet, with complete mask, hood or full suit."

3. NICKEL

3.1. Exposure limits: status and trends

There is at present no exposure limit (expressed in terms of concentration) as regards the presence of nickel in the environment, arising from industrial or urban discharges. In fact the industries liable to discharge substantial quantities of nickel into the environment, like all classified installations (ICPE), are required to obtain discharge permits, which will define amounts of discharges that must not be exceeded. At present however, no target limit on the nickel concentration in the ambient air has been defined.

The approach to limiting exposure to airborne nickel forms part of a European perspective. In fact, on 27th September 1996, the European Union adopted a framing directive on the evaluation and management of air quality (directive AQA/M 96/62/EC). This directive lays down general guidelines for member states for managing air quality, notably as regards the production of information, the formulation of schemes to improve air quality, monitoring effects on health and the environment, and so on. In Annex 1 of this directive, 13 agents are listed as priority pollution indicators, one of which is airborne nickel.

Each of the agents set out in this directive is to be the subject of a "daughter directive" which will determine in particular the concentration limits for the quality of the ambient air. These limiting values are usually defined on the basis of the health effects that may result from the presence of these agents in the ambient air. An initial daughter directive was recently proposed for the following agents: SO2, NOX, PM10 dust and lead (a second is under preparation for benzene). This draft directive includes concentration limits in the ambient air that must not be exceeded with different thresholds: annual mean value, and additional values for shorter periods (from a few days to one hour). Once the daughter directive has been adopted, member states will have up to 2 years to transfer it into their own regulations. Also, depending on the urgency of the objectives given in terms of concentration in the environment, the deadline dates by which these limiting values must be achieved (which are therefore objectives to be reached in terms of air quality) are either 2005 or 2010. By that time, for areas exceeding the limiting values, schemes for reducing the concentrations must be prepared and submitted regularly to the European Commission. As far as nickel is concerned, the daughter directive should be discussed in the near future.

In fact the directive clearly states that the limiting values in terms of concentration in the ambient air are based upon the WHO recommendations for air quality in Europe (Air Quality Guidelines for Europe - WHO, 1996). In the case of nickel, the WHO has proposed, on the basis of epidemiological studies and extrapolations to low levels of exposure, an estimate of the risk of lung cancer of 9.6 10-4 for continuous whole life exposure to 1 µg/m3. On this basis the WHO, without directly proposing a limiting value for nickel, indicates that a concentration of 10 ng/m3 of total airborne nickel would made it possible to abide by a whole life cancer risk of 10-5. However since the estimated risk proposed by the WHO is giving rise to discussions (lower risk values are also proposed), the limiting concentration of nickel in the environment could be of the order of a few tens of ng/m3 depending on the results of the discussion.

3.2. Monitoring discharges and concentrations in the environment

3.2.1. Monitoring concentrations in the environment

Atmospheric pollution due to nickel is still little known and the monitoring of concentrations in the environment is highly fragmentary. At European level, a number of schemes have been set up to provide a knowledge base and an understanding of the mechanisms whereby nickel is transferred over long distances. So far three French cities - Paris, Strasbourg and Rouen - have seen measurement campaigns. However with the adoption of the Law on air quality (Law N°96-1236 of 30 December 1996) which represents the transfer into French regulations of directive AQA/M 96/62/EC, the details of environmental surveillance and the preparation of schemes to improve air quality have been defined.

Pending the adoption of the daughter directive on nickel by the European Union, nickel has not yet been covered in French law and is therefore not one of the substances measured. For other substances, threshold values (in terms of concentration in the ambient air) are proposed with warning levels according to the periods considered and a measurement obligation by fixed stations has been introduced in cities with population more than 100,000 and areas where there is a risk of heavy pollution.

An air quality scheme will be established in each region and this will include the monitoring of nickel. In addition, depending on the zones involved, this regional scheme may encompass the introduction of surveillance of health effects. Depending on the pollution levels reached and the size of the population, epidemiological studies may be proposed in conjunction with the national public health system.

3.2.2. Monitoring atmospheric discharges around installations

With regard to atmospheric discharges of nickel, all the installations classified for the protection of the environment (ICPE) that require permits must abide by the discharge limits set out in the Ministerial Order of 2nd February 1998. The requests for discharge permits are handled by the DRIRE. For nickel, the values presently defined in the Order are: if the total hourly flow for the sum total of a list of substances[39], including nickel and its compounds, exceeds 25 g/h (for channelled and diffuse emissions), then the concentration limit in the emissions facility is 5 mg/m^3

If discharges of nickel exceed 500 g/h, then the operators themselves must make continuous measurements of the rate of discharge.

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[39] The substances in question are: antimony, chromium, cobalt, copper, tin, manganese, nickel, lead, vanadium, zinc and their compounds

3.3. The objectives in terms of "best available technologies" and air quality and the optimisation principle

3.3.1. The role of the best available technologies

According to the Decree of 2nd February 1998, which takes up the IPPC directive (Directive 96/61/EC of 24th September 1996), it is specified that the discharge limits are defined "on the basis of the use of the best available technologies at acceptable economic cost and of the particular characteristics of the environment" (Article 21). Accordingly a European working group was set up to prepare recommendations in terms of the best available technologies for the different sectors of activity concerned by atmospheric discharges of nickel. It is specified however that the discharge (or emission) limits are to be defined "without requiring the use of a specific technique or technology" (IPPC Directive).

3.3.2. The introduction of regional air quality schemes

The regional air quality schemes, provided for in the Law of 30th December 1996, are drawn up by Prefects, assisted by the Regional Environment Committee, the Health Councils of the *départements* and representatives of approved organisations. Consultation of the public and the local and regional and elected representatives should make it possible to ensure that all those involved locally do participate. This scheme is initially intended for a period of 5 years, after which it is reviewed and revised if necessary.

In addition to this network for monitoring concentration in the ambient air, the Law on air quality requires an evaluation of the health (and environmental) effects of air quality. This evaluation is intended both to improve knowledge of pollution levels and the links with the health effects and, if necessary, to suggest developments as regards surveillance. This is a new approach which integrates the evaluation of health risks into environmental management. This scheme should make it possible:

- to evaluate the effects on health (identifying health effects related to pollutants; characterisation of exposure; estimates of risks) ;
- to define objectives for reducing health effects by setting priorities according to the local situation and plans for reducing health risks pending action to reduce pollution;
- to improve surveillance by measurement campaigns and facilitate public information.

To prepare and monitor the regional air quality scheme, committees chaired by Prefects have been set up, comprising:

- representatives of government departments (DRIRE, DIREN (regional environment directorate, DRE (regional infrastructure directorate), DRASS and ADEME);
- representatives of regional groups (regional and general councils);
- representatives of activities that contribute to the emission of pollutants (industry, local communities, etc.);
- representatives of air quality surveillance bodies and environmental protection associations and other groups of consumers or users;
- representatives of the regional environment committee and departmental health councils.

It appears that the structure proposed for the implementation of the regional air quality schemes is such as to create an arena for local transactions between the different actors in defining priorities and the steps to be taken for improving air quality. In particular this structure should make it possible to make the connection between the ambient air concentration targets to be reached and the objectives in terms of reducing local and regional emissions. Accordingly the search for an air quality specific to the region is equivalent to a search for a reasonable concentration level seeking to achieve a consensus between the different actors having regard to regional interests.