Collaboration agreement between the Nuclear Safety Council and the Carlos III Institute of Health

Epidemiological study of the possible effect of ionising radiations deriving from the operation of Spanish nuclear fuel cycle facilities on the health of the population living in their vicinity

Summary of the final report

December 2009

Environmental and Cancer Epidemiology Unit, National Centre for Epidemiology

Nuclear Safety Council

TABLE OF CONTENTS

Note 1. This report has been drawn up by the Carlos III Institute of Health (ISCIII) and the Nuclear Safety Council (CSN), each within its respective realm of competence and function as regards the issues dealt with. The CSN is responsible for all aspects relating to the reconstruction of the history of exposure of the population to ionising radiations arising from the operation of the facilities and to those of natural origin. The ISCIII is responsible for the design and performance of all aspects of the cancer mortality study and for drawing up all the sections of the report referring to this issue.

Note 2. In order to facilitate understanding, a glossary of technical and scientific terms used in the report has been included as an appendix thereto.

EXECUTIVE SUMMARY

Introduction and background

Echoing a social demand regarding the impact of nuclear facilities on the health of persons, the Plenary Session of the Spanish Congress approved a Motion during its meeting of December 9th 2005 urging the Government to carry out a study considering the following aspects, among others:

- *The scope of the study should include all the nuclear facilities and surrounding areas, with an analysis of their possible effects on the health of the population.*
- *The CSN should collaborate by providing the information required to assess the exposure of the population to radiations of both artificial (facilities) and natural origin.*
- *There should be a guarantee of independence in the research and of maximum transparency in the performance of the activities. With this aim in mind, it was decided to set up an "Advisory Committee", with the participation of the involved institutions, independent experts, environmental groups and other stakeholders, for tracking of the performance of the study and analysis of its results.*

For the performance of the study, the Carlos III Institute of Health and the Nuclear Safety Council signed a Collaboration Agreement in April 2006. The study commenced as of that date and extended to the end of 2009.

The Advisory Committee was set up in September 2006 and included a wide range of organisations: the health authorities of all the Autonomous Communities or regions affected by the geographical scope of the study, trade union organisations, municipal authorities, the companies owning the facilities, environmental conservation organisations and six independent experts (epidemiology, radiobiology and radiological protection), along with representatives of the Carlos III Institute of Health and the CSN. The Committee has met on six occasions to deal with methodological aspects, the results of the dose estimates and the data and results from the analysis of mortality and aspects relating to communication and the dissemination of the study.

Basic characteristics of the study

Scope

The study includes all the nuclear power plants and other nuclear fuel cycle facilities in the country, regardless of whether they are in operation, in the final shutdown condition or in the phase of dismantling and decommissioning.

The study area includes all municipal areas located within a radius of 30 km around the facilities, the situation of which is compared to the municipalities located in a control zone, with similar socio-demographic characteristics but unaffected by the operation of the facilities.

In addition, cancer mortality has been studied in municipalities located in two geographic areas characterised by different exposure to natural radiations and not affected by the influence of any fuel cycle facility. Specifically, the municipalities were selected in two areas with a radius of

30 km, one in the autonomous community of Galicia, with high exposure to natural radiation, and the other in the autonomous community of Valencia, subject to low exposure to natural radiation.

In total more than 1,000 municipalities have been studied, 500 of which are located in the area of influence of the facilities. The rest are municipalities in the control zones and in the two geographical areas with high and low exposure to natural radiation.

Methodology

The methodology of the study is that defined by the ISCIII in keeping with the current practices considered to constitute the "state of the art". It is an ecological study of retrospective cohorts in which the mortality due to different types of cancer and leukaemia among the residents in all the municipalities located around the Spanish facilities (30 km) is compared with that found in the municipalities used as reference (50 to 100 km). The study period is 1975-2003.

The study is ecological because the central variable for analysis, exposure to radiation, is assessed by means of an indicator, effective dose, estimated for each population group formed by the residents in each municipal area, and is assigned to the individuals in this group (no individualised study for each person is performed).

The exposure indicator used is "effective dose" as this parameter provides clear benefits that are especially significant in the case of far-scope and wide spectrum studies such as this. Consideration has been given to the limitations involved in using effective dose as an indicator of exposure in epidemiological studies. This approach has been explicitly endorsed by the International Commission on Radiological Protection (ICRP) in response to a query from the CSN.

The historical reconstruction of the exposure of the population in each municipality has been accomplished by means of an internationally recognised methodology based on estimating the dose to the population as a result of the discharges of liquid and gaseous effluents from the facilities. Theoretical estimation models have been used with parameters adjusted to the specific characteristics of each geographical area in which each facility is located and representative of an "average individual".

As regards exposure to natural radiation, the annual dose received by an inhabitant in each of the municipalities has been estimated those around the facilities and in control areas and those in the two geographical areas of Galicia and Valencia outside the influence of the facilities.
Other important characteristics of the study:

- *For all the cancers studied, with the exception of the leukaemias, a period of ten years (induction) has been considered as the minimum necessary for the individual affected by an exposure to radiation to develop the illness. This period has been considered to be one year in the case of the leukaemias.*

- *Consideration has been given to the variables that may act as factors of confusion, that is to say those that might alter the results of the study. Among these are exposure to ionising radiations of natural origin and various socio-demographic factors.*

- *Other exposures to ionising radiations of artificial origin, such as occupational exposures and those received during medical treatment and diagnosis, have not been taken into account.*

Cancer mortality has been analysed jointly for all the nuclear power plants on the one hand and for all the other fuel cycle facilities on the other hand, and each of the facilities has been analysed individually. Furthermore, cancer mortality has been analysed in relation to exposures to radiations of natural origin, both in the areas of influence of the facilities and in the two zones selected outside these areas.

Considering the population in the municipalities and the study period, more than 8 million persons-year have been accounted for in the areas surrounding the nuclear power plants for leukaemias, and more than 5 million persons-year for other tumours. In the areas surrounding fuel cycle facilities the study has accounted for 8.5 million persons-year and 6.4 million persons-year for leukaemias and other cancers, respectively.

Results

Facilities / artificial radiation
The accumulated doses that it is estimated would be received by the population as a result of the operation of the facilities are very low, the maximum value being 350 microSievert (the dose limit established for members of the public in the Spanish regulations is 1,000 microSievert in any one year).

Both in the joint analysis of the areas of influence of the nuclear power plants and in the analysis corresponding to the other fuel cycle facilities, no consistent results are observed that show any increase in cancer mortality associated with dose. Furthermore, the individualised studies of each facility do not give any results indicating any increase in such mortality, with certain specific observations that it has not been possible to attribute to the effect of the doses generated as a result of their operation since:

- *In general these are isolated findings that are not repeated at the rest of the facilities, for which reason they are not consistent.*

- *The doses estimated in the surrounding area as a result of the operation of each facility are very low and similar to those for other installations at which the same effects are not observed.*

- *Certain fuel cycle facilities present exposure situations with characteristics common to those occurring in certain locations due to natural radiation (isotopes, transfer routes, incorporation in the organism), the exposure to natural radiation being several orders of magnitude higher and no effect associated with it being observed in the analyses performed.*

- *These occasional results might be attributed to other forms of environmental exposure due to differences in lifestyle or the presence of other industries and activities, or might simply be random. In view of the large number of comparisons performed, this in itself explain a certain number of positive associations (which might also explain certain* *negative statistical associations, i.e., with a reduction in mortality with increasing radiation dose, that have occasionally been observed).*

Natural radiation

The cancer mortality studies performed in both the areas surrounding the facilities and in those not affected by them, located in two geographical areas with different levels of exposure to natural radiation, have not detected any statistically significant increases in mortality with increasing dose.

Conclusions

- *The estimated accumulated doses that would have been received by the population in the study areas as a result of the operation of the facilities are very low and far below those that, in the light of current scientific knowledge, might be related to effects on the health of persons.*

- *No consistent results have been detected that show any effect of increasing mortality due to different types of cancer associated with the exposure of persons to ionising radiations arising from the operation of the facilities. Certain occasional dose-response associations have been found but it has not been possible to attribute these to the exposure deriving from the operation of the facilities.*

- *Neither have statistically significant excesses in cancer deaths due to natural radiation been detected.*

INFLUENCE OF NUCLEAR FUEL CYCLE FACILITIES ON MORTALITY DUE TO CANCER IN PERSONS LIVING IN THE VICINITY OF SUCH FACILITIES IN SPAIN

1. INTRODUCTION AND OBJECTIVES

During its session of December 9th 2005, the Spanish Congress approved a motion urging the Government to undertake a new epidemiological study in areas housing nuclear facilities and including, among other things, the history of exposures to artificial and natural radiation in the vicinity of these facilities, information which would be provided by the CSN. For the performance of this study information mechanisms should be established guaranteeing the independence of the research and transparency in the performance of the activities, and an Advisory Committee should be set up for the tracking and discussion of the results on completion of the study.

In Spain certain studies have been performed on the health of populations living in the areas surrounding nuclear fuel cycle facilities. One of the limitations of these studies, shared by many of the studies carried out in other countries, springs from the use of the distance separating the municipality of residence from the facility as a measure of exposure. This way of classifying individuals assumes an equivalence between artificial radiation dose and distance that implies a bias of misclassification, reducing the capacity to detect a possible risk associated with exposures deriving from the facilities studied.

An original contribution made by this epidemiological study is the analysis of cancer mortality in relation to a quantification of the exposure of the population to ionising radiations arising from the operation of the facilities and radiations of natural origin, this providing an added value compared to the majority of the studies of this type that have been performed in the rest of the world. Very few previous epidemiological studies have reconstructed the exposure history of the population, the cases studied in most cases having been very limited in their scope and as regards the effects investigated.

In order to assess the possible influence on the health of the population living in the vicinity of the Spanish nuclear fuel cycle facilities, it is necessary to estimate the exposure to **radiations** deriving from the operation of these installations. The exposure history of these populations may be reconstructed by using information gleaned from the control of discharges of radioactive effluents and the environmental radiological surveillance carried out in the areas close to the facilities.

An additional source of exposure to be taken into account is the radioactivity of natural origin. The exposure to ionising radiations (IR) of this type constitutes the main source of exposure for the general population and might have an influence on mortality or modify the possible effect of the exposure deriving from the effluent discharges from the facilities, this being an issue to be considered in the design and analysis of this type of epidemiological studies.

The Nuclear Safety Council (CSN) is the body that coordinates the system of environmental radiological surveillance networks existing in Spain. The radiological data from all these networks are stored in environmental radiological surveillance databases, this providing an updated bank of environmental data capable of supplying reference levels at any moment. These measurements, which are the best tools available to ascertain the actual values of radiological exposure, are generally lower than the detection levels. As a result, the CSN estimates the exposure of the population to the emissions of radioactive effluents from the facilities, a critical point that determines the feasibility of the study described herein, by means of complex calculations that consider factors such as the types of emissions, the diffusion of contaminants, etc. This estimate, which is accomplished on the basis of the releases from the facilities, allows the municipalities to be classified by their dosimetry history.

In April 2006, the Carlos III Institute of Health and the Nuclear Safety Council signed a Collaboration Agreement for the performance of the study requested by the Congress, with the following **general objectives**:

> Study of cancer mortality in municipalities located in the vicinity of the Spanish nuclear power plants and other nuclear fuel cycle facilities on the basis of the history of exposure to the emissions arising as a result of the operation of these facilities, comparing them to the data for other Spanish municipalities having similar socio-demographic characteristics but not located in the vicinity of nuclear facilities.
>
> Likewise, a comparison will be made between the mortality for these same causes in two areas selected on the basis of their characteristics of exposure to natural radiation and not subject to the influence of nuclear or radioactive facilities.

The study has been performed under the necessary conditions of scientific rigour and transparency, with an Advisory Committee having been set up for detailed and independent tracking of the study, in particular as regards the methodology applied, analysis of the results and communication and dissemination. This Advisory Committee is made up of a wide spectrum of representatives of organisations having an interest in the study: the health authorities of all the Autonomous Communities or regions affected by the geographical scope of the study, trade union organisations, municipal authorities, the companies owning the facilities (electricity industry, Enresa and Enusa), environmental conservation organisations and independent experts, along with representatives of the Carlos III Institute of Health and the CSN.

2. MATERIAL AND METHODS

2.1 Design of the epidemiological study

The study in question is an ecological study of retrospective cohorts in which the mortality due to cancer among the residents in all the municipalities located in the vicinity of the Spanish facilities (30 km) is contrasted against that encountered in other municipal areas used as controls. The study encompasses the period 1975-2003. The study is: 1) **ecological**, since the central variable analysed is the exposure to radiation estimated for population groups such as those living in the aforementioned municipalities and 2) of **retrospective cohorts** since it reconstructs the exposure history of the populations on the basis of their respective dates of birth and monitors the incidence of mortality among them up to the year of completion of the study. Consequently, the basis for the study is constituted by the populations of municipalities within a distance of 30 km around the Spanish nuclear power plants and other fuel cycle facilities, regardless of whether these installations are in operation or in the phase of dismantling (Table 1). Other municipalities having similar socio-demographic characteristics and located in the same geographical area, but sufficiently far from the facilities (50 to 100 km) were selected as a reference or control. Consideration is given also to the populations of municipalities located in two selected zones, in high and low natural radiation areas respectively, not subject to the influence of the operation of the facilities.

Selection of municipalities in the vicinity of nuclear facilities and control municipalities

Table 1 shows the facilities that are included within the scope of this work.

Table 1. Nuclear power plants and fuel cycle facilities studied

Facility	Start-up	Location
Nuclear power plants		
José Cabrera	1968	Guadalajara
Santa Mª de Garoña	1971	Burgos
Vandellós I	1972	Tarragona
Almaraz, Group I	1981	Cáceres
Almaraz, Group II	1982	Cáceres
Ascó, Group I	1983	Tarragona
Cofrentes	1984	Valencia
Ascó, Group II	1985	Tarragona
Vandellós II	1987	Tarragona
Trillo, Group I	1988	Guadalajara
Fuel cycle facilities		
Andújar uranium mill	1959	Andújar (Jaén)
Sierra Albarrana low and intermediate level radioactive waste disposal facility (El Cabril)	1993	Hornachuelos (Córdoba)
Lobo-G uranium ore treatment plant	1977	La Haba (Badajoz)
Elefante uranium concentrates manufacturing facility	1978	Saelices el Chico (Salamanca)
Juzbado uranium oxide fuel manufacturing facility	1985	Juzbado (Salamanca)
Quercus uranium concentrates manufacturing facility	1993	Saelices el Chico (Salamanca)

The study focussed on municipalities located within a radius of 30 km around each facility. For each municipality located within this radius of 0-30 km a control municipality was selected at random from among all those located at a distance of 50-100 km from the facility and fulfilling at least 5 of the 6 conditions for comparison imposed, based on the number of inhabitants, percentage of unemployed, percentage of illiterate people, percentage of the employed or unemployed population previously working in agriculture, level of income and province.

Selection of municipalities in two areas with different levels of exposure to natural radiation

Two areas located within a radius of 30 km were selected using the cartography generated in the MARNA project (natural radiation map), one in the south of Galicia and the other between the provinces of Valencia and Alicante. The first of these is an area with a high level of natural radiation due to the granitic composition of its soil and the second is a very low natural radiation area.

Causes to be studied

In view of the universal nature of its occurrence, mortality is currently the only indicator that may be used to monitor the health situation and study the possible long-term influence on health of residing in the vicinity of the Spanish facilities overall. Although registers of the occurrence of cancer have been established in certain Spanish provinces, there is no register covering the entire State and the coverage provided by those that do exist is insufficient for the study of the incidence of cancer to be included in this project.

For each municipality located in the vicinity of the facilities included in this study, consideration is given to the number of deaths caused by different types of cancer, by age group, gender and year for the period 1975-2003. For the municipalities in the areas studied in relation to natural radiation, the study period is 1994-2203 (the last ten years of the study). The tumours selected for study are as follows (considering periods of induction of 1 year for leukaemias and 10 years for the rest:

Table 2. Types of cancer selected for the study

CIE-9	Location	CIE-9	Location
151	Stomach	189	Kidney
153, 154, 159.0	Colorectal	191	Brain
162	Lung	192	Other CNS tumours
170	Bones	193	Thyroid
171	Conjunctive tissue	200, 202	Non-Hodgkin lymphomas
174	Breast (woman)	201	Hodgkin lymphomas
183	Ovary	203	Myeloma
186	Testicle	204-208	Leukaemias
188	Bladder		

CIE-9 International Classification of Illnesses, 9th revision
All cancers have been included regardless of their radioinducibility.

2.2 Estimation of exposure to ionising radiations in the vicinity of the facilities included in the study

Selection of an indicator of exposure for each municipality included within the scope of the study

The surveillance required to protect the public in the vicinity of NPPs and other fuel cycle facilities is accomplished by estimating the doses that might be received by individuals in the area as a result of the radioactive effluents released by the facilities.

The present epidemiological study has been set out as an ecological study, the indicator of exposure selected being **effective dose**1, for both the emission of effluents by the facilities and exposure to natural radiation.

A retrospective estimate has been made of the doses accumulated by the population in each municipality in the area as a result of the effluents released by the facilities since the beginning of their operation. In addition, the doses due to natural radiation in these same municipalities and in those used as a reference have been estimated. This amounts to approximately 87% of

A glossary of terms has been drawn up and may be consulted in the main report total annual exposure when average values are obtained for the entire world population, with a high degree of territorial variability.

The magnitude of **effective dose** brings benefits to performance of the study in terms of simplicity, representativeness and specificity. Furthermore, the methodology used in its estimation is contrasted and practically standardised internationally. These benefits are especially significant in a study with a spectrum as ample as that of the one described herein, where the initial aim is to identify possible apparent associations between exposure and mortality due to cancer. Where existing, these potential associations should be the subject of more detailed studies, following estimation of the absorbed doses.

It should also be taken into account that the magnitude of **effective dose** has certain limitations as regards its use in epidemiological studies, since it presents an averaged information on exposure that is not suitable for detailed quantitative risk assessments. Furthermore, it does not provide information on the exposure of specific individuals but rather for a standard reference person in a situation of exposure to radiation; consequently, it does not provide information on the risk for each specific individual but for everybody in a group in general.

In its 2007 recommendations the International Commission on Radiological Protection (ICRP) indicates that the use of effective dose is inappropriate for epidemiological studies, where the absorbed doses in individual organs and tissues should be used (ICRP publication 103).

The CSN consulted with the ICRP on the use of effective dose as an indicator of exposure in a study such as this. The ICRP replied that this would be acceptable if the uncertainties and limitations involved in using a magnitude of protection such as effective dose were clearly set out and no far-reaching conclusions were obtained regarding individual risks as a result of such a study. The ICRP pointed out that studies based on effective dose might be useful for the identification of apparent correlations that might be studied in greater detail using another methodology.

In view of all the above, the decision was taken to use the magnitude of effective dose in the specific context of the current epidemiological study and with the aforementioned limitations. The analyses performed to decide on the exposure indicator to be used in the present study included the participation of the stakeholders through the Advisory Committee established for the tracking of the study.

Estimation of artificial radiation doses to the members of the public in the vicinity of the nuclear power plants and fuel cycle facilities and doses due to natural radiation

In view of the fact that the levels of radioactivity obtained from environmental surveillance programmes are very low, in general below the detection levels, organisations responsible for the radiological protection of the public and the environment, such as the CSN, make use of estimation methodologies aimed at providing a series of values that, under certain hypotheses, may be considered representative of the magnitude of the impact on the public in terms of dose. This does not mean that the results obtained actually represent the true dose received by the individuals in question but rather that they constitute an approximate value for this dose oriented towards an objective, in most cases of a regulatory nature.

The models used by the CSN in the study are in keeping with international practices for calculation of the dose to the population included by the International Atomic Energy Agency (IAEA) in its Safety Report Series No 19 (SRS-19) (IAEA, 2001). The atmospheric dispersion model used is Gaussian in type with negligible diffusion, complete reflection in the soil and constant conditions of turbulence in each period of integration. The aquatic dispersion model assumes complete and instantaneous mixing downstream of the point of discharge, except in the case of sites located on the sea shore, where the dilution of the radionuclides takes place in a strip measuring 370 metres in width along the coast.

The concentrations of radionuclides in the physical environment of the facilities (air, water, soil) having been established, it is necessary to reproduce the processes by which these radionuclides reach the individuals in the population, through direct impact and via the food chain. These mechanisms constitute the so-called exposure ways, the properties of which will be characteristic of each site:

- For effluents released to the atmosphere (gaseous effluents), consideration has been given to external exposure (to both the cloud and the deposits accumulated on the ground) and incorporation into the organism through inhalation and the ingestion of contaminated foodstuffs, of both vegetable (wide-leaved plants and potatoes, cereals and others) and animal (meat and milk) origin.

- As regards the effluents released to the aquatic medium (liquid effluents), consideration has been given to external exposure to sediments on the banks, the ingestion of drinking water and the ingestion of fish (river or sea species, as the case may be) and shell fish and other contaminated foodstuffs of animal or vegetable origin, as in the previous case.

As regards natural radiation doses, the calculations have adhered to the methodology set out in the UNSCEAR 2000 report. The exposure ways considered have been as follows:

- Cosmic radiation
- Terrestrial gamma radiation
- Inhalation of radon and thoron
- Internal exposure to other natural isotopes due to the ingestion of water and foodstuffs.

The estimates have been expressed as average values of the effective dose received by the inhabitants of each municipality and have been obtained using the best information available for each of the parameters involved in the calculation (best estimate calculations) instead of using conservative values (which tend to overestimate exposure).

The experimental data involved in the calculation come from different CSN projects and, in certain cases, from independent studies published by different research groups. Likewise, new surveillance campaigns have been performed, designed specifically to provide the information required for the epidemiological study. In the case of variables with a very minor contribution and for which no local data are available (such as for example exposure to thoron or radioactivity in foodstuffs), national or world averages or parameterisations provided by UNSCEAR have been used.

Criteria for the establishment of cut-off points

Although the accumulated doses due to radiations of artificial origin are extremely low, there is a certain amount of variability and, in order not to impose any assumption on the way of relating exposure to mortality it has been considered appropriate to work with the variable categorised. This means that the intervals of exposure are first defined through the use of estimated dose cut-off points and the population groups with estimated exposure doses included in one same interval are considered jointly.

The categorisation method used aims to optimise the detection of statistical associations between dose and mortality, reducing the possibilities of inadequate classification as a result of cut-off points being established in areas of continuous distribution of effective dose. In this respect, attempts have been made to identify natural jumps or cut-off points in dose distribution, preventing strata with similar doses from being classified in different categories. The objective was to achieve categories that were heterogeneous one with respect to the next (with the differences between doses in different categories being greater than those observed within any one same category), imposing restrictions guaranteeing the stability of the estimators through as homogeneous as possible a distribution of the members of the population. As a result of the above, different dose intervals have been established for the joint analysis of the nuclear power plants, on the one hand, and the radioactive facilities of the fuel cycle on the other, as well as for the individual analysis of each facility. These intervals are shown in tables 5 and 6 in the section on results.

2.3 Analysis of mortality

For all the municipalities included in the study, the deaths occurring as a result of the causes studied are tabulated for each study period, age group and gender, this information being obtained from the individual records provided by the National Institute of Statistics (INE).

Different methods have been used to estimate the risk of dying from cancer in the study areas. All the methods used are based on the assumption that the number of deaths due to cancer in each age stratum and period is distributed as a Poisson statistical variable. The central variable of the study is radiation dose. The relative risks of mortality are used as a measurement of effect, estimated either in terms of mortality rate (the mortality rate is the number of deaths divided by the persons-year being tracked) between exposed and unexposed population groups (rate ratio) or in terms of SMR (Standardised Mortality Ratios), i.e. comparison between the cases observed and those that would be expected if the municipalities had the same mortality as the general population.

Special attention has been paid in evaluation to those results that show statistically significant increases in the relative risk of mortality as a result of the different cancers with higher exposure to radiation. In epidemiology this is what is known as dose-response analysis. The parameters calculated to determine dose-response associations are 1) the relative risks for each level of exposure and 2) the relative risks considering exposure to be a continuous variable. In order to determine whether this dose-response association is statistically significant, in addition to checking that the relative risk increases with exposure, a tendency check is applied, this providing a value of probability (p-value). This p-value is considered to be significant when it is below 0.05. In the analysis in which the variable of exposure is continuous, a mortality rate ratio **RR** is provided (per unit of the variable), along with a 95% confidence interval . If this confidence interval does not include the unit, it is said to be statistically significant. In general, finding this effect in both analyses provides greater consistency in the result and it is important to observe the way in which risk increases with dose with the variable categorised.

The effective doses estimated (table 3) for the population of the municipalities represent the annual average dose that would have been received by a typical individual for each municipality under study. This estimate is provided year on year. The accumulated radiation dose has been calculated by cohort of birth (generation) and this allows analysis to be performed in terms of accumulated average dose.

As has been shown by previous studies, the distribution of mortality due to cancer in Spain is particularly heterogeneous. Many of the cancer locations that are included in this project show clear geographical inequalities and the simple comparison of mortality between two provinces may provide rate ratios higher than 2. For example, if we compare the age adjusted mortality rate due to lung cancer in 2004 in Cáceres to that for Guadalajara, we obtain a rate ratio of 1.91. In most cases the causes of this geographical heterogeneity are unknown. The conditions of comparison change when a 'local adjustment' such as that proposed is used. The municipalities in a specific area are compared to similar municipalities, in terms of population and environment, in the same area. This perspective allows for greater control of geographical heterogeneity as a factor of confusion in these models, comparing more homogeneous areas.

In this project the variable of exposure is the same in physical terms regardless of the population studied. However, each facility has a specific and unique history that makes it necessary to undertake its analysis separately. The joint analysis of facilities of one same type (nuclear power plants on the one hand and fuel cycle facilities on the other) is also possible and makes it possible to determine whether there is heterogeneity in the effect observed at the different installations. In joint analysis consideration is given to the variable 'facility', which is included in the models as a random effects term. Heterogeneity between facilities has been evaluated in terms of the statistical significance of the interaction between accumulated artificial radiation dose and facility, in a fixed effects model.

Table 3. Range of accumulated artificial radiation and annual natural radiation doses in the municipalities located in the vicinity of each of the plants and facilities

	0-30 km **No municipalities**	**Accumulated artificial radiation** **Dose range microSievert**	**Annual natural radiation** **Dose range microSievert**
Nuclear power plants			
José Cabrera	60	0.1015159 – 267.50550000	2031 – 2837
Santa Mª de Garoña	68	6.518255 – 303.6069090	1770 – 2280
Vandellós (I and II)	46	0.07105639 – 203.05685500	1928 – 2627
Almaraz	33	0.01881667 – 27.58200000	2340 – 5840

Ascó (I and II)	65	0.0302446 – 5.69964000	1819 – 2786
Cofrentes	19	0.02841531 – 2.62450000	1695 – 3730
Trillo	62	0.04578781 – 10.63200000	1752 – 2040
TOTAL	328*	0.01881667 – 303.6069090	1695 – 5840

Fuel cycle facilities

Andújar	22	2.909576 – 348.47300000	1917 – 2470
El Cabril	9	0.00043568 – 0.00296800	2705 – 4198
La Haba	26	8.138715 – 138.13900000	2577 – 20103
Saelices El Chico	44	19.88334 – 289.12300000	3431 – 15413
Juzbado	76	0.00001500 – 0.05791200	2416 – 5112
TOTAL	177	0.00001500 – 348.47300000	1917 – 20103

Note: Vandellós and Ascó share 25 municipalities located at a distance of less than 30 km from the two facilities. For this reason the total number of municipalities included (328) does not correspond to the sum of the municipalities in the vicinity of the nuclear power plants (353). In subsequent tables the total number of municipalities does not agree with those shown in this table since consideration has been given to the segregations occurring during the study period, which has made it necessary to add the individuals together for their analysis.

3. RESULTS

General comments on the study population, socio-demographic characteristics and categories of radiation dose

Table 4 shows the general characteristics of the persons included in the study for each facility including: the populations according to the 1991 census, the persons-year taken in to account for the operating period of each facility (considering induction periods of 1 and 10 years), the average of the socio-demographic characteristics and the average number of inhabitants per municipality in the years 1991 and 2001.

Table 4. General characteristics of the population studied in areas adjacent to the facilities

	Population [1]	Aged less than 25 years [1]	Persons/year (in thousands) [2]	Persons/year (in thousands) [3]	% Illiterate	% Unemployed	% Farmers	Income	Average population 1991	Average population 2001
Nuclear power plants (*)										
Zorita (1968)										
0-30 km	25816	7305	807,1	684,0	5,6	10,4	22,7	6,2	461,0	481,4
50-100 km	29914	9293	943,7	825,8	4,5	10,9	18,8	6,5	564,4	819,7
Garoña (1971)										
0-30 km	57625	20236	1977,8	1549,8	1,3	13,4	12,7	6,7	992,3	974,3
50-100 km	50060	15475	1477,3	1159,8	1,1	14,7	23,4	7,0	725,7	702,6
Vandellós (1972)										
0-30 km	73594	26161	2705,7	1901,3	3,1	13,5	16,8	6,2	2628,4	3177,6
50-100 km	43373	14675	2814,4	2046,5	2,6	12,9	11,3	6,6	1606,4	1788,7
Almaraz (1981)										
0-30 km	47637	17672	1051,4	624,5	5,4	30,3	32,7	5,6	1488,7	1527,2
50-100 km	45946	16390	1019,3	597,3	5,2	27,5	31,0	5,8	1584,3	1571,8
Ascó (1983)										
0-30 km	49049	13410	967,4	468,0	1,9	10,7	27,1	6,5	876,7	817,9
50-100 km	61594	19275	1322,6	719,3	2,1	9,7	23,5	6,6	1162,2	1455,1
Cofrentes(1984)										
0-30 km	35881	11733	351,8	161,2	4,0	17,8	16,8	6,8	1888,5	980,5
50-100 km	71975	27159	1424,9	701,0	4,0	19,0	10,6	6,1	4498,4	5061,9
Trillo (1988)										
0-30 km	13259	3312	195,6	61,8	3,2	11,2	25,5	5,4	232,6	214,1
50-100 km	12976	3392	188,3	59,9	2,4	11,4	26,2	5,7	231,7	212,2
Total										
0-30 km	302861	100075	8056,8	5450,6						
50-100 km	315838	105702	9190,5	6109,6						
Fuel cycle facilities										
Andújar(1959)										
0-30 km	126063	50411	3660,5	3660.5	8,4	22,4	30,7	5,1	6003,0	6038,3
50-100 km	152673	58224	4472,5	4472.5	8,8	21,6	31,8	5,3	7270,1	7410,5
El Cabril (1961)(1993)**										
0-30 km	38781	13545	441,9		9,7	34,8	25,2	5,1	4309,0	4291,9
50-100 km	44373	18114	405,1		10,2	35,6	39,0	4,5	5546,6	5637,1
La Haba(1977)										
0-30 km	111456	41790	2947,2	1913.1	6,2	27,5	26,5	5,5	4458,2	4426,6
50-100 km	151289	59682	3952,3	2624.3	6,0	26,5	21,0	5,6	6051,6	6146,5
Saelices El Chico (Pl.Elefante 1978)										
0-30 km	32276	9393	780,5	460.1	2,7	18,7	24,2	5,8	733,6	641,4
50-100 km	35848	10556	853,4	508.5	2,1	19,9	19,8	5,7	833,7	718,3
Juzbado(1985)										
0-30 km	32627	11151	650,3	325.5	0,8	16,2	26,9	5,6	429,2	614,8
50-100 km	36713	10832	637,5	265.4	1,2	16,6	30,1	5,8	476,8	415,1
Total										
0-30 km	341203	126290	8480,4	6359.3						
50-100 km	420896	157408	10320,8	7870.7						

* Year of entry into service

1 Census for 1991

2 Persons-year considering a period of induction of 1 year

3 Persons-year considering a period of induction of 10 years. Income is a summary indicator ranging from 1 to 10.

** The radioactive wastes produced by the former Nuclear Energy Board (JEN) began to be stored at El Cabril as from 1961. The installations that make up the current facility began to operate in 1993, the dosimetry data provided corresponding to the period since that time.

Plants: The study covers 328 municipalities within 0-30 km and 174 within 50-100 km.

Fuel facilities: 177 municipalities within 0-30 km and 174 within 50-100 km.

The study takes into account a total 5 million persons-year in the exposure area and similar number in the area of reference for a 10-year period of induction in the vicinity of the nuclear power plants. As regards the fuel cycle facilities, 6.4 million and 7.9 million persons-year are taken into account in the exposure and reference areas, respectively. The socio-demographic indicators are similar in both study areas and for each of the facilities. In view of the dose data provided, 1993 is considered to be the year of start-up in the case of the El Cabril disposal facility.

In the case of the nuclear power plants, 328 municipalities located within the 0-30 km radius have been included in the study, and 303 within a radius of 50-100 km. For the fuel cycle facilities, these figures were 177 municipalities in the 0-30 km radius and 174 within 50-100 km.

Tables 5 and 6 show the artificial radiation dose categories used in the analysis for each facility along with the proportion of the population exposed to more than 10 microSievert, for induction periods of 10 and 1 years respectively.

Table 5. Categorisation of artificial radiation doses (latency of 10 years)

a) **Ranges of accumulated dose by categories (microSievert)**

	Reference	d1	d2	d3	d4	%exp> 10microSv
Nuclear facilities						
José Cabrera	0	0,007-0,12666	0,12924-0,25086	0,25699-1,8829	2,35655-265,4788	18,3
Garoña	0	0,00527-10,474	10,54109-36,2971	37,551-45,4275	45,6033-303,55452	80,7
Vandellós	0	0,00053–0,25523	0,26074–11,556	85,813-142,7687	166,5072-176,5683	58,7
Almaraz	0	0,00076-0,03316	0,03796-0,08249	0,08671-0,10207	0,10782-21,158	3,6
Ascó	0	0,00561-0,0215	0,02232-0,0858	0,09376-0,80486	0,9686-3,60264	0
Cofrentes	0	0,01178-0,03198	0,03454-0,07208	0,0741-0,17016	0,1877-2,2544	0
Trillo	0	0,00031-0,03041	0,0326-0,05768	0,0605-0,2048	0,2309-3,576	0
Facilities overall	0	0,00076-0,1800	0,18444-2,5357	2,72775-44,0380	44,80000-303,5545	45,9
Fuel cycle facilities						
FUA	0	0,01435-0,9441	1,13083-22,81907	25,85175 - 67,849	70,255 - 335,523	61,3
El Cabril						0
La Haba	0	0,14638-4,9101	5,312 - 14,8336	15,2736 – 34,599	35,991 - 114,93	67,9
Saelices el Chico	0	0,34687-2,9779	3,037 - 4,8736	4,907 - 15,7612	16,267 - 40,423	38,6
Juzbado	0	>0 – 0,00001	0,00001–0,00002	0,00002 – 0,00005	0,00005 - 0,03991	0
Facilities overall	0	0-2,11140	2,1870 - 17,18551	17,7625 - 50,48980	52,0290-335,52300	58,5

Table 6. Categorisation of artificial radiation doses (latency of 1 year). Ranges of accumulated dose by categories (microSievert)

Facility	Reference	d1	d2	d3	d4	% exp >10 microSv
José Cabrera	0	0,001-0,14561	0,14693-0,28233	0,28765-2,0145	2,2833-267,2675	17,7
Garoña	0	0,00106-8,5709	9,0491-35,7096	36,5959-45,7637	45,8965-303,60581	78,9
Vandellós	0	0,00038-0,23774	0,24126-2,99783	13,7207-145,2483	161,0132-201,13685	56,9
Almaraz	0	0,00057-0,06512	0,06792-0,09107	0,09375-0,16572	0,17413-27,184	4,3
Ascó	0	0,00237-0,03143	0,03264-0,0993	0,10262-0,8826	1,00024-5,58364	0
Cofrentes	0	0,00423-0,03883	0,0403-0,09804	0,1063-0,16036	0,1779-2,5822	0
Trillo	0	0,01357-0,06201	0,06328-0,10469	0,10944-0,29207	0,31301-10,119	1,1
Facilities overall		0,00041-0,11156	0,11239-1,58295	1,61190-42,95300	43,97026-303,60581	39,7
FUA	0	0,01458-7,1672	7,6205-44,857	48,1775-107,3714	112,2658-347,213	69,7
El Cabril	0	0,00014-0,00039	0,00042-0,00073	0,00081-0,00096	0,00113-0,00263	0
La Haba	0	0,0382-9,1462	9,4213-15,4564	15,755-47,822	50,068-137,474	71,5
Saelices el Chico	0	0,27737-3,1833	3,279-14,787	15,1337-65,296	68,3192-274,923	60,3
Juzbado	0	>0 – 0.00002	0,00002-0,00004	0,00004-0,00007	0,00007-0,05691	0
Facilities overall		=> 2,24265	2,28520-18,24800	18,45577-57,85000	59,51200-347,21300	54,9

The highest levels of accumulated artificial radiation exposures are to be found among the populations in the vicinity of the Garoña and José Cabrera facilities, although these never reach 350 microSievert; in any case the estimated levels of exposure are extremely low. The same occurs in the vicinity of the fuel cycle facilities, where the Andújar Uranium Mill is particularly outstanding in terms of estimated dose, although accumulated dose values of 350 microSievert are not encountered in any of the municipalities in the vicinity.

Table 7 shows the annual natural radiation doses categorised by quartiles for each facility.

Table 7. Categories of annual natural radiation doses by facilities in microSieverts (quartiles)

	C1	C2	C3	C4
José Cabrera	2030 - 2250	2260 - 2410	2420 - 2680	2700 – 4250
Garoña	1670 - 1910	1920 - 2050	2060 - 2160	2190 – 3230
Vandellós	1930 - 2160	2170 - 2260	2270 - 2410	2420 – 2850
Almaraz	2340 - 2970	2980 - 3150	3180 - 3870	3970 – 5840
Ascó	1780 - 2020	2030 - 2170	2180 - 2260	2270 – 2790
Cofrentes	1480 - 1650	1680 - 1940	2100 - 2180	2210 – 3730
Trillo	1750-1940	1950-2030	2040-2630	2650-3620
FUA	1480 - 2020	2050 - 2100	2110 - 2200	2210 – 3840
El Cabril	1600 - 1960	2020 - 3200	3270 - 3350	3400 – 4180
La Haba	1830 - 2120	2130 - 2490	2580 - 3770	3780 – 20100
Saelices el Chico	2570 - 3800	3830 - 4040	4050 - 4420	4430 – 15410
Juzbado	1740 - 2980	3000 - 3650	3670 - 4230	4240 – 5400

Comments on the magnitude of artificial radiation doses and their distribution by nuclear power plants and fuel cycle facilities

The range of annual estimated doses due to the effluents released by the nuclear power plants for the population in the 328 municipalities located in the vicinity of these facilities is from 0.000017 microSievert/year to 73.4 microSievert/year with an arithmetical mean value and typical deviation of 0.64 and 3.8 microSievert/year, respectively. In the vicinity of the fuel cycle facilities this range is from 0 to 72.4 microSievert/year with an arithmetical mean value and typical deviation of 1.39 and 3.52 microSievert/year, respectively.

In view of the differences in the order of magnitude between the natural radiation doses and those produced by each installation, a comparative analysis has been made between the two. The conclusion of this analysis is that in no case does the proportion of the annual effective dose due to the effluents exceed 0.15% of the total effective dose (the sum of the doses due to radiations of natural origin and those due to effluents).

The accumulated effective doses due to artificial radiation are extremely low, although in the vicinity of certain facilities they are higher than in others, with no overlapping between them. The difference between the municipalities with the lowest and highest accumulated effective doses amounts to 5 orders of magnitude and their distribution among the different installations is not similar. This is due to the higher emissions that took place during the early years of operation of the three oldest plants, Vandellós I, José Cabrera and Garoña. For this reason the accumulated doses in the municipalities in which these facilities are located are in the upper part of the range; the municipalities in the vicinity of the Almaraz, Ascó and Trillo plants are in the middle part of the range (from 0.01 to 10 microSievert) and the estimates for Cofrentes are in the lowest band. It should be pointed out that the doses estimated for the municipalities around Vandellós are due to the releases from both Vandellós I and Vandellós II, which would explain why this area presents the highest number of municipalities with dose values at the lower and upper ends of the range. As regards the fuel cycle facilities, the municipalities in the vicinity of Juzbado show lower doses that do not overlap with those corresponding to the rest of the installations.

The spatial distribution of the artificial radiation in the areas around the facilities is not uniform (isotropic) and is strongly conditioned by geographical features and, especially, by rivers and the coast in the case of Vandellós.

As regards the fuel cycle facilities, the areas surrounding the Andújar, La Haba and Saelices El Chico installations are those in which the estimates of the radiation doses deriving from the emissions of effluents give the highest values, although the estimated accumulated doses have not exceeded 350 microSievert, in other words they have been negligible. In the areas around El Cabril and Juzbado there has hardly been any exposure.

Results of joint analysis of the nuclear power plants

Before analysing the possible relationship between cancer mortality and the estimated doses, an analysis was performed of mortality prior to and following the start-up of each nuclear power plant in the 0-30 km area (results not shown in this summary). The only statistically significant differences as regards a differential increase in the standardised mortality ratio between the exposure and reference areas (50-100 km) occur for breast cancer in women in the vicinity of Vandellós and for colorectal cancer around Almaraz. Both types of tumours are closely linked to socio-economic development, diet and lifestyle. As this is a general descriptive analysis that considers only the date of start-up of the facilities, they cannot be stated to be related in any way to the operation of the aforementioned plants.

Table 8 shows the results of the joint analysis for the nuclear power plants, linking mortality due to different cancers to the estimated accumulated doses of artificial radiation.

The table shows the number of deaths included in each exposure category and the mortality rate ratios for each category compared to that of the reference zone, in addition to two statistical trend tests. In the analysis of the tumours studied for both sexes, no increase in the mortality rate ratios with dose is observed in either the analysis of categorised dose or the analysis of dose as a continuous variable, since all the intervals of confidence include the unit. The only exception is cancer of the kidney. The trend test is statistically significant, but the way in which the mortality rate ratio (**RR**) varies with dose category is not coherent. What is observed is that in the category with the highest exposure, the **RR** is higher. All the estimates are adjusted by age, natural radiation categorised in quartiles and socio-demographic variables.

The results of the mortality analysis for each facility do not reflect increases in mortality rate ratio with dose, although there are certain specific issues observed that are indicated below. In the area of José Cabrera no statistically significant association is detected, although in the case of multiple myeloma all the **RR**'s are above the unit and in the 2nd and 3rd category there is a statistically significant excess mortality. In the category with the highest exposure to artificial radiation, however, there is a reduction in risk with respect to the two aforementioned categories which reduces the credibility of the association.

In the case of Garoña, no statistically significant increase in risk with dose is detected. An exception to this is cancer of the kidney when analysed as a continuous variable. However, in analysis with the dose variable categorised, the pattern shown by the estimators by categories does not reflect an effect of increase with dose.

At Vandellós a statistically significant increase in lung cancer mortality is observed in association with dose. The populations included in the category with the highest exposure show a level of mortality that is higher than in the reference area. This result explains the result obtained from joint analysis of the plants for the parameter p-value, the indicator of the heterogeneity of the results from the different plants for this cancer.

In the area surrounding Ascó, a higher level of mortality as a result of non-Hodgkin's lymphoma is observed, with a statistically significant trend test. The mortality is highest in the category with the highest exposure; it should be taken into account, however, that this cancer is rarely associated with radiation.

At Almaraz, Cofrentes and Trillo there are no results warranting detailed comment. In the case of the last two of these plants, a low number of deaths is recorded, since these are the two facilities with the lowest number of persons-year of monitoring.

The significance of the aforementioned aspects is analysed in section 4; consideration should be given to the issues indicated therein in order to be able to draw conclusions regarding all these aspects.

Table 8. Joint analysis of all nuclear power plants

Results of analysis

a) number of deaths by categories of exposure (estimated accumulated artificial radiation doses);

b) rate ratios (**RR**) by categories of accumulated artificial radiation doses and tendency test;

c) **RR** for accumulated dose per 10 microSievert taken as a continuous variable, 95% interval of confidence;

d) test of homogeneity of relative risk by facilities.

RR by dose, the reference being the population of the municipalities located in the 50 to 100 km area.

Natural radiation has been included categorised and as a factor since no linear effect is shown. Estimates obtained from a mixed regression model including the plants as a random effects term. Estimates adjusted by natural radiation, age and socio-demographic variables and restricted to the period of operation.

	Deaths					RR d1	RR d2	RR d3	RR d4	Tenden value-p	RR dose	IC	95%	Homogeneity value-p
Dose category microSievert	d0 ref	d1	d2	d3	d4	0,00076-0,18	0,18444- 2,5357	2,72775- 44,038	44,80-303,5545					
Lung cancer	2022	569	448	300	631	0,900	0,910	0,800	0,970	0,525	1,001	0,994	1,009	0,009565
Bone cancer	56	19	11	10	20	1,250	0,700	0,540	0,960	0,694	0,995	0,954	1,038	0,126
Cancer of CNS	311	69	85	63	89	0,770	1,100	0,830	0,840	0,268	0,991	0,973	1,008	0,3165
Thyroid cancer	36	5	7	1	11	0,440	0,830	0,140	1,250	0,232	1,003	0,947	1,063	0,07199
LNH	217	61	63	22	77	1,010	1,170	0,520	1,070	0,306	1,012	0,994	1,031	0,04603
Hodgkin	27	5	11	5	11	0,560	1,460	0,800	1,110	0,776	0,988	0,936	1,044	0,369
Myeloma	150	44	42	22	50	1,020	0,950	0,940	0,980	0,993	1,007	0,985	1,029	0,8593
Cancer of the bladder	485	138	133	81	188	1,060	1,060	0,710	1,030	0,394	0,999	0,986	1,013	0,07386
Conjunctive	39	14	17	4	12	1,350	1,890	0,460	0,870	0,618	0,973	0,922	1,027	0,763
Kidney cancer	204	59	49	36	83	0,890	1,040	0,880	1,390	0,009	1,019	1,000	1,038	0,1561
Stomach cancer	1092	264	218	316	348	0,850	0,870	0,970	1,010	0,555	1,000	0,990	1,010	0,00213
Colorectal cancer	1369	434	388	231	414	1,070	1,100	0,880	0,950	0,380	0,995	0,986	1,003	0,416
Cancer of the testicle	7	1	1	0	1	0,320	0,630	0,000	1,060	0,822	1,028	0,903	1,169	0,5252
Breast cancer	690	176	194	140	249	0,920	1,070	1,050	1,070	0,621	1,005	0,993	1,016	0,09429
Cancer of the ovary	166	62	52	30	46	1,270	1,230	1,060	0,810	0,129	0,980	0,956	1,005	0,515
Dose category microSievert						0,00041-0,11156	0,11239-1,58295	1,61190-42,953	43,97026-303,60581					
Leukaemias	502	121	159	78	132	0,960	0,970	0,910	0,930	0,620	0,999	0,985	1,013	0,2756

* The dose categories for leukaemias are different due to the period of induction of 1 year

Results for fuel cycle facilities

Table 9 shows the results of the joint analysis for the nuclear fuel cycle facilities, relating mortality as a result of the different cancers to the estimated accumulated artificial radiation dose. As in the case of the nuclear power plants, the table shows not only the number of deaths included in each exposure category but also the mortality rate ratios for each category compared to that of the reference zone. These data reflect an increase in mortality with estimated radiation dose for the following tumours: lung cancer and bone cancer. Furthermore, in these cases and in the case of leukaemias, the analysis of exposure as a continuous variable is also statistically significant. In the case of lung and bone cancer, the rate ratios (specific estimator) for all dose intervals are higher than the unit in the joint analysis for both sexes and in the analysis for men only; in the case of leukaemias this circumstance occurs in the analysis for women only. The heterogeneity test is statistically significant in lung cancer and colorectal cancer.

The statistical association between dose and mortality in the case of lung cancer appears to be present in both men and women, while for bone cancer and leukaemias this association is statistically significant only for women.

The results of the joint analysis would appear to be conditioned by the results corresponding to the area surrounding the Andújar Uranium Mill (FUA). In the analysis by facilities, excess mortality may be observed for this installation for lung and colorectal cancers and leukaemias (the latter at the limit of statistical significance) when the categorised variable is analysed. However, when this variable is treated as continuous, only colorectal cancer from among the aforementioned tumours is statistically significant, to which bone cancer should be added. In this case it is appropriate to observe the pattern of change of the rate ratios in the area of exposure, since although an increase of mortality with dose is observed for colorectal cancer, in the case of lung and bone cancers, and despite the fact that mortality in all the exposure categories is higher than that of the reference area, no dose-response effect is appreciated with exposure in the specific estimator of risk.

In the vicinity of the Andújar facility (FUA), mortality by gender has been analysed in detail due to the existence of a previous study of cohorts that underlined the existence of risk associated with occupational exposure to radiations for the workers of the former Nuclear Energy Board in charge of uranium processing. The impact of these occupational doses on the results of the present study is considered to be very much a minor one because of the small number of people who worked at the FUA. Furthermore, in this type of situations, and especially for lung cancer, observing what happens in the case of women is particularly indicative of whether this might be an effect associated with environmental exposure, because of the small number of women that smoked in the generations previous to 1940 in Spain. Excess lung cancer mortality is not observed among women; excess bone cancer mortality , however, is observed only among women. The mortality pattern for leukaemias is also clearer in women, although not statistically significant.

As it has been pointed out for the joint analysis of the nuclear power plants, the significance of the aforementioned aspects is analysed in section 4, and consideration should be given to the issues indicated therein in order to be able to draw conclusions regarding all these aspects.

Table 9. Joint analysis of fuel cycle facilities

Results of analysis

a) number of deaths by categories of exposure (estimated accumulated artificial radiation doses);

b) rate ratios (**RR**) by categories of accumulated artificial radiation doses and tendency test;

c) **RR** for accumulated dose (per 10 microSievert) taken as a continuous variable, 95% interval of confidence;

d) test of homogeneity of relative risk by facilities.

RR by dose, the reference being the population of the municipalities located in the 50 to 100 km area. Estimates obtained from a mixed regression model including the plants as a random effects term. Estimates adjusted by natural radiation, age and socio-demographic variables and restricted to the period of operation. Both sexes

	Deaths						RR d1	RR d2	RR d3	RR d4	Tenden value-p	RR dose	IC	95%	Homoge value- p
Dose category MicroSievert	d0 ref	d1	D2	d3	d4		<=2,1114	2,187 - 17,18551	17,7625 – 50,4898	52,029- 335,523					
Lung cancer	2812	477	789	522	725		1,190	1,250	1,310	1,340	0,000	1,008	1,001	1,014	0,01046
Bone cancer	81	25	17	15	27		1,610	1,120	1,290	1,860	0,049	1,041	1,005	1,078	0,3301
Cáncer de CNS	322	46	90	59	66		0,760	1,320	1,140	1,030	0,704	0,993	0,973	1,013	0,09253
Thyroid cancer	34	5	13	10	5		0,830	1,290	1,880	0,840	0,993	0,990	0,919	1,066	0,377
LNH	235	39	71	34	45		0,960	1,310	1,050	1,070	0,179	0,998	0,973	1,024	0,9098
Hodgkin	61	8	13	12	11		0,620	1,210	1,180	1,140	0,602	1,044	0,998	1,091	0,407
Myeloma	181	40	43	32	35		1,360	0,790	1,080	0,770	0,206	0,998	0,974	1,022	0,348
Cáncer of the bladder	633	92	160	84	133		0,930	1,100	0,960	1,020	0,926	1,001	0,987	1,014	0,4293
Conjunctive	67	7	18	7	11		1,050	1,490	0,850	1,030	0,828	0,995	0,943	1,049	0,1102
Kidney cancer	264	66	73	46	60		1,500	1,010	1,060	1,110	0,789	0,994	0,971	1,018	0,4594
Stomach cancer	1427	293	313	206	248		0,850	0,810	0,850	0,970	0,777	1,003	0,992	1,015	0,05479
Colorrectal cancer	1568	282	504	259	373		1,030	1,230	1,030	1,110	0,407	1,004	0,996	1,012	0,01977
Cancer of the testicle	10	0	8	2	1		0,000	2,640	1,120	0,520	0,671	1,070	0,947	1,210	0,9293
Breast cancer (women)	887	150	231	141	198		1,050	1,200	1,140	1,230	0,087	1,001	0,989	1,014	0,02319
Cancer of the ovary	203	36	65	38	48		1,320	1,360	1,260	1,080	0,921	0,996	0,974	1,019	0,2235
Dose category microSievert							<=2,24265	2,2852 – 18,248	18,45577 – 57,85	59,512 – 347,213					
Leukacemias*	636	105	156	116	155		0,980	1,060	1,220	1,130	0,144	1,012	1,001	1,022	0,2614

Study of the possible effect of natural radiation in the vicinity of the facilities

Natural radiation has been categorised in quartiles and the rate ratios of each quartile have been calculated through comparison with that presenting the lowest exposure (first quartile). The estimates have been adjusted by age and socio-demographic variables.

In this analysis it is not possible to use an estimate of accumulated exposure since the variable of exposure is a constant. The accumulated exposure is the annual dose multiplied by age and the categorisation of the accumulated variable will show us simply the effect of age since it would compare the oldest individuals with the youngest. Age is the most important risk marker for cancer since the incidence of the latter increases exponentially with age. Taking this dependence between accumulated dose and age into account, the most logical type of analysis would be a comparison of the mortality rates in areas with the highest annual levels of natural radiation with that observed in the areas with the lowest annual levels of natural radiation.

No statistical associations of interest have been found in any of the analyses performed, either with the variable categorised or assuming a linear effect (continuous variable). The results are negative when the operating period of the facilities is considered and also when the entire study period is taken into account.

Study of the possible effect of natural radiation in high and low exposure areas

The study includes a comparative analysis of cancer mortality in two areas of high and low natural radiation. The high natural radiation area is located in the south of Galicia and the low radiation area includes municipalities in the provinces of Valencia and Alicante.

The analysis covers a period of 10 years (1994-2003). As the variable of exposure is constant with time for each municipality, it is not necessary to take the induction period into account.

Mortality has been compared in two areas (high and low natural radiation) for the different tumours under study, with the estimate adjusted for age, period and socio-demographic variables. In this analysis, a higher rate of mortality is observed in the area in Galicia (area of higher exposure) than in the area located in Valencia (lower exposure) among both men and women and for lung and stomach cancer. Among the men, Galicia also shows excess mortality for non-Hodgkin's lymphoma and colorectal cancer. Nevertheless, it should be borne in mind that the two geographic areas are very different one from the other, not only as regards the magnitude of the natural radiation but also as regards other risk factors linked to lifestyle, such as diet, tobacco and alcohol consumption and the presence of other environmental and/or occupational exposures.

In this case the analysis has also been performed with the annual dose due to natural radiation categorised by quartiles in the two areas. The natural radiation in the two areas does not overlap since the range in the high natural radiation zone is from 4270 to 5850 microSievert, while in the low radiation area it is from 1250 to 2230 microSievert. No association has been found between the mortality due to the different tumours analysed and the estimated natural radiation dose.

Assessed overall, the results referring to natural radiation are negative. No pattern of change is observed in the cancer mortality rates in relation to natural radiation in any of the analyses performed, either in the vicinity of the fuel cycle facilities and plants or in the specific study of the high and low natural radiation areas.

4. DISCUSSION

Certain of the more relevant aspects of the results obtained from the study are commented on below.

In general terms, the results of the joint analyses for all the facilities to determine the possible relationship between cancer mortality and exposure to the artificial radiation deriving from the operation of these installations are negative, which is only to be expected in view of the low levels of accumulated exposure obtained from this study, which in no case exceed 350 microSievert. At such low doses it is not to be expected that any effect will be observed, in the light of current knowledge. Indeed, no consistent pattern of increasing cancer mortality may be observed accompanying any higher level of exposure deriving from the normal operation of the facilities. Although certain occasional and possible increases in mortality relating to higher radiation doses are observed, these increases are not repeated at the different installations, this removing consistency from the possible existence of a relationship with the exposure doses.

When attempting to explain these statistical associations, it should be borne in mind that the information available does not allow other risk factors of relevance as regards cancer genesis to be considered in analysis. Before concluding that the occasional mortality excesses observed are directly attributable to artificial radiation, it would be necessary to take these other factors into account.

Epidemiological studies are always subject to possible sources of bias. The classical classification of these biases is in terms of selection, information (assessment and classification of exposure), confusion (the influence of other factors not considered) and analysis, all of which are to be discussed in this study.

As regards selection, the identification of the basis of the study has been determined by the decision to include all the municipalities located within a radius of 30 km from each facility. This radius is the one used in the environmental surveillance plans for the areas surrounding the nuclear power plants. As references, a series of municipalities comparable to the 'exposed' areas in terms of socio-demographic variables (number of inhabitants, percentage of unemployed, percentage of illiterate individuals, percentage of farmers, level of income and province) and located at a sufficient distance from each nuclear facility were included. Although the objective of the comparison used in selecting the reference municipalities is for these areas to be as similar as possible, in order to reduce the possible effects of confusion, the study has not taken into account important aspects of individual exposures in the populations compared (habits and occupational or environmental exposures resulting from the surroundings).

In discussing the results of the study, the validity of the dose estimates performed by the CSN plays a central role, since it constitutes the main original contribution to the study.

In estimating the effective doses, conservative values overestimating exposure have been selected for the parameters used when values more in keeping with the actual conditions were not available. In the case of the estimates of doses due to ingestion, a more realistic approach has been used, with mean values being selected for the consumption of different foodstuffs. Overall, the methodology used is conservative for estimation of the effective dose of the overall population of each municipality.

In addition to the uncertainties inherent to the dose estimation methodologies themselves, particular mention should be made of those relating to determination of the source term at the fuel cycle facilities, for which specific periodic information on the activity and isotopes released has not been available in certain cases. In such cases an overestimate of the source term has been applied in accordance with the nominal design values of the process and safety systems (i.e., maximum capacities in the case of the FUA) or the mineral removed and processed has been taken into account on the basis of its grade (Lobo-G plant). Obviously, in these situations the necessary calculation hypotheses are affected by additional conservatism.

Finally, a major source of uncertainty – possibly the most important since it directly establishes a relationship between cause and effect – relates to quantification of the effect that ionising radiations have on the health of persons; i.e., the factors for conversion to dose. The values accepted by the international community and included in the national legislation (RPSRI, 2001) have been used, except in the case of dose arising from external exposure due to deposits on the ground, where it has been necessary to use other sources (EPA, 2002). In the case of radon (the main contributor to dose due to natural radiation and by inhalation at uranium mining facilities), for example, the uncertainty associated with the dose conversion factor is 100% according to the ICRP (ICRP, 1993).

The spatial distribution of the data by dose categories differs from the radial pattern produced by distances, as used in previous studies, since consideration has been given to the specific characteristics of each site and land and water use in the area. The classification errors will vary depending on the facility. Although for certain facilities, and as a result of the pattern of distribution of the dose estimates, distance might be a good approach (e.g., Garoña), for others this will not be the case. At certain of the facilities the tests on agreement between classifications indicate that the probability of misclassifying each of the municipalities exceeds 50% when distance is used as an indicator of exposure. An example of the consequences of these classification errors might be the results for mortality due to multiple myeloma in the area around the José Cabrera plant, where in the previous study, using distance as the indicator, an excess mortality due to this cancer was observed in the study area (0-30 km). However, this excess is not associated with the distribution of the estimated artificial radiation doses, the highest rates being detected in municipalities located in lower exposure categories.

The analysis has been based on comparison between the mortality rates in different categories of exposure to radiation and the reference category. Consideration has been given to the year of uptake by each cohort of the population in each municipality to estimate its accumulated doses. In the case of artificial radiation it is assumed that dose will be zero in municipalities located more than 50 km from each facility. Quartiles have been used in the categorisation of natural radiation. All the estimators of risk have been adjusted by age, period and socio-demographic variables included by design and by natural radiation. In analysis by categories the dose-response tests have been applied by using the mid-way estimated dose point in each interval, since this is the recommended method in this type of analysis. All the models that presented an extra-Poisson dispersion have been corrected to adapt the amplitude of the intervals of confidence to the actual distribution of the data. In the joint analysis of the facilities, mixed models have been used in which the variable facility considered as the random effects term constitutes a form of stratification that, in addition to bringing robustness to the effect estimators, takes into account the geographical heterogeneity of cancer mortality in Spain.

The use of estimated doses includes a component of uncertainty in exposure additional to ecological assignment. Although it is recommended that this uncertainty be taken into account in analysis, in practice it is quite difficult to do this because of the need to have available information on the distribution of the uncertainty for doses between the different population groups.

Other forms of exposure of ionising radiations, such as occupational exposure or that corresponding to diagnostic medical checks (the largest anthropogenic source of exposure to ionising radiations) cannot be taken into account in this type of studies since information on them is available only at individual level or averaged at national level.

As regards the assessment of the results encountered in the municipalities close to certain facilities, the presence of other types of polluting industries in the vicinity of each of the facilities may be of interest. This information has been obtained from the EPER register (national register of polluting sources and emissions).

The Ascó nuclear power plant is very close to the Ercros electrochemical plant in Flix. Different studies have been carried out in this municipality and the exposure of the population to hexachlorobenzine and other organochlorated compounds possibly associated with NHL's has been documented.

Five industries are registered on the EPER in the vicinity of Garoña. Two of these belong to the chemical sector, one is involved in paper production, one is a thermal power plant and one is a hazardous waste tip. Four of these are located in Miranda del Ebro, at a distance of 26 kilometres from the plant.

Three types of exposure come together in the vicinity of uranium concentrates production facilities. Although occupational exposure occurs at all the facilities, in mining activities the personal protection of the workers was scarcer in the 1960's and 70's; exposure of the population in general as a result of emissions, where the component of chemical toxicity would outweigh the radiological; and finally the deposits of tailings, which are also toxic. The environmental exposure to ionising radiations in this type of installations has similar characteristics to exposure to natural radiation (isotopes, exposure pathways, uptake by the organism). The fact that no statistically significant results associated with very high natural radiation doses are found removes credibility from the occasional findings associated with artificial radiation doses for these facilities.

Eleven polluting industries are located in the area surrounding the Andújar Uranium Mill (FUA). Most of these (8) belong to the minerals industry (manufacturing of ceramics and bricks), the remainder being two tips and one paper mill. The ceramics and bricks manufacturing industry is characterised by strong emissions of SO2, fluorine and particles (PM10). This type of emissions might add to the exposure deriving from the processing of uranium and might partly explain the higher mortality rate due to lung cancer, although no association with higher mortality due to bone cancer and leukaemias has been described. The excess mortality due to lung cancer is not observed among women and might, therefore, be an effect relating to occupational exposure and/or differential habits (tobacco consumption). It should be borne in mind, however, that the number of workers at the FUA was always very small compared to the total population residing in the area, for which reason it is difficult to attribute the results to the influence of occupational exposure at this facility. Excess mortality due to bone cancer is observed only among women, where all the estimators are above the unit. Certain radionuclides, such as barium, strontium, radium and transuranic elements are osteotrophic. Furthermore, it should also be taken into account that the accuracy of bone cancer certification improved in the mid 1980's when the coding of the certificates was transferred to the Autonomous Communities, although the possible influence of this certification improvement on the results obtained is not known.

The impact of these polluting industries on cancer mortality in the areas studied is very difficult to assess and individualising the risks deriving from each is even more complicated.

These three aspects, in addition to others mentioned below, might explain the results relating to the uranium concentrates production facilities, especially in the area around Andújar.

Although the study has not shown significant results as regards natural radiation, understood as the sum of terrestrial gamma radiation, cosmic radiation, diet and the radiation from radon and thoron (inside and outside buildings), the etiological role of radon in lung cancer among miners was described years ago and more recently this description extended to the possible increase in the risk of exposure to very low dose levels in homes, although exposure in the home represents less than half the total exposure received by the general population. The CSN's estimates for exposure to natural sources of radiation for the Spanish population are: terrestrial gamma radiation (30%), cosmic radiation (18%), radiation from radon and thoron (34%) (interior and exterior of buildings) and ingestion (18%).

The most widely accepted opinion at present is that the negative dose-response association arising from the ecological studies contradicts the results of the analytical studies and should, therefore, be rejected. In Spain, the high spatial resolution maps of mortality due to tumours show a pattern among women in which mortality due to lung cancer is higher in areas of southern Galicia, with high levels of natural radiation, where the composition of the ground is granitic and where granite is preferably used as a building material. This pattern among women is also observed in coastal areas in A Coruña and Lugo, for which reason exposure to radon would be a plausible explanation for this result. However, in analysis of the study restricted to the high natural radiation area in the province of Pontevedra, the results do not support the possible existence of a relationship between exposure to natural radiation and mortality due to the tumours studied.

The study dealt with in this report has several strengths that should be remembered. The main strength, and one of the original elements of the study, is the performance of an epidemiological study that includes the reconstruction of the dosimetry history of the populations. This task had been suggested on several occasions but, to the best of our knowledge, has not previously been addressed in other countries through studies having the scope of the one described herein. These radiation dose determinations show the anisotropy of the exposure and make it possible to overcome the limitations of those models that use distance to the source as the measure of exposure.

Despite the approaches associated with the use in certain cases of generic data and the aforementioned methodological uncertainties, the dose estimates performed may be demonstrated to be reliable, since they have been accomplished using an internationally accepted methodology in keeping with the state-of-the-art, and the results are coherent with those obtained for this type of installations across the world. The dose estimates considered in this study constitute an upper limit for the exposures actually received by the population, both those resulting from the operation of the facilities and those due to radiation of natural origin.

The study contains an important number of persons-year over the period of operation of the facilities, this increasing the possibility of detecting associations were they to exist (statistical power). The study has been conceived as a retrospective ecological study of dynamic cohorts in which doses have been taken into account from the moment of incorporation of the population up to exit or death. This has allowed accumulated artificial radiation doses to be analysed with consideration given to generations.

Another of the strengths of the study is the use of categories of exposure that recognise the natural distribution of doses by maximising the 'jumps' between categories. In view of the low magnitude of the doses, their assignment to population groups and the uncertainty present in the estimates, categorisation is the most suitable procedure for their analysis. Robust methods have been used in the analysis to estimate the intervals of confidence of the effects, which might be considered a conservative procedure, although on the other hand no corrections of values-p have been carried out to take into account the large number of hypothesis tests performed (correction by multiple comparisons). In the absence of associations between estimated dose and mortality due to any type of cancer, it is still possible to find a certain percentage of statistically significant associations due exclusively to random. The percentage of spurious positive associations to be expected with the limits of significance used is 2.5%.

Another strength of this study of great interest has been its performance under conditions of transparency, to which has contributed the Advisory Committee set up for its tracking, with all the factors relating to the design and performance of the study and the aspects relating to public communication and dissemination discussed.

As regards the weaknesses of the study, it should be pointed out again that it is a study of mortality and that for pathologies such as leukaemias it would be more suitable to use information on incidence, information that is not available in most of the areas of analysis. However, in the results referring to the nuclear power plants, no indications suggesting excess mortality as a result of these pathologies are observed.

When interpreting the results it should be borne in mind that the radiosensitivity of human tissues for the induction of cancer is variable (UNSCEAR 2000). The cancers that are frequently associated with radiations in the scientific literature, with consistent estimates of risk, are: leukaemias, those deriving from the mammary tissue when exposure occurs prior to menopause and those affecting the thyroid gland among young people. The tissues that would appear to be less susceptible or in which cancers are induced at relatively high doses include the lung, stomach, colon, oesophagus, bladder, ovaries, brain and nervous system and liver. The cancers rarely associated with radiation and with uncertain risk estimates are those affecting the kidneys, salivary glands, non-Hodgkin's lymphoma, myeloma, skin, rectum, uterus, bone and conjunctive tissue. Those that have not shown any association, or have shown this only sporadically, are chronic lymphatic leukaemia, cancer of the pancreas, Hodgkin's lymphoma, prostate cancer, cancer of the testicles, cervical cancer and certain cancers affecting children. This type of classification is revised periodically depending on the publication of research results. This report has included cases of all the categories described. However, the positive results of our study are not observed in the more radiosensitive tumours; in other words, the few associations found between estimated dose and mortality for a given type of cancer do not consistently affect the more susceptible tissues.

In the analysis, the way in which the possible confusion factors may be controlled is very much limited by the availability of information, the clearest case being tobacco consumption, since it is associated with many of the tumours studied. The study is ecological in nature, this meaning that the indicators of municipal exposure are applied to the entire population and that there may be an ecological bias.

Another limitation of interest is the impossibility of finding ways to validate the estimated doses, in both the environmental and the biological areas, which would contribute theoretically to greater security regarding assessment of the results. It should be borne in mind that environmental measures are generally below the detection limits, this making it possible to ensure that the actual values are zero or insignificant, in view of the extremely high sensitivity of this type of measures. Consequently, if no radioactivity is detected in the transfer pathways, it would be senseless to perform specific individual controls aimed at gaining insight into the doses received by the population. These controls would require dosimeters to be carried and imply being subjected to periodic controls of excreta and corporal radioactivity, which would not be justified in any case in view of the extremely low magnitude of the dose.

In view of its design and the availability of information, the study has not been able to take into account demographic phenomena such as migrations, and in assigning doses the populations have been assumed to be stable in the different municipalities.

In epidemiological terms, the problem of the chemical toxicity of artificial radionuclides has been studied very little in human populations and might be a route to be considered to explain phenomena that do not fit with current radiobiological understanding.

Set out below are the main conclusions of the epidemiological study carried out in the areas of influence of the Spanish nuclear power plants and other fuel cycle facilities and in two areas not affected by these facilities and subject to different levels of exposure to ionising radiations of natural origin. The study has been performed using an internationally contrasted scientific methodology and under conditions of transparency, with the supervision of an independent Advisory Committee.

5. CONCLUSIONS

1. This study shows that, using realistic methods of estimation, the doses of artificial radiation accumulated over the entire study period that would have been received by the population as a result of the operation of the facilities are very small. Current understanding of radiobiology and epidemiology does not suggest that this exposure might be related to a higher degree of cancer mortality in the populations existing around the facilities.

2. In general terms, the study of cancer mortality in the areas surrounding the nuclear power plants and nuclear fuel cycle facilities has not detected any consistent results showing any effect of increasing mortality due to different types of cancer and associated with the artificial radiation dose received. These results are independent from the natural radiation and other socio-demographic variables controlled in the analysis.

   Certain dose-response relationships have been found in the study, limited to a certain type of cancer and to a certain type of facility. These results would not appear to be due to the exposure deriving from the operation of the facilities, since these findings are not repeated at other installations of the same type and with similar characteristics of exposure. In view also of the low radiation doses estimated, it would be necessary to look for an explanation for these relationships in other possible sources or additional forms of environmental exposure, or even random.

3. Assessed overall, the results referring to natural radiation do not reflect any relevant contribution. No pattern of change may be observed in cancer mortality rates relating to natural radiation in any of the analyses performed, neither in the vicinity of the nuclear power plants and fuel cycle facilities nor in the specific study of high and low natural radiation areas.