Bundesamt für Strahlenschutz

Technical Report

The German Uranium Miners Cohort Study (Wismut cohort), 1946–2003

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Content

1 SUMMARY

BACKGROUND

From 1946 – 1990, i.e. from shortly after the end of World War II and the rise of the cold war until the German reunification, there had been extensive uranium mining both in Saxony and Thuringia, which formed the southern parts of the former German Democratic Republic. Mining activities started in Saxony in the Ore Mountains (German: Erzgebirge). Mining was conducted by a Soviet, since 1954 by a Soviet-German Incorporated Company named Wismut. It is estimated that about 400,000 persons may have worked in this time period with the company, most of them underground or in uranium ore processing facilities. In the early years, exposure to radiation and dust was particularly high for underground workers. After introduction of several ventilation measures and wet drilling from 1955 onwards, the levels of exposures to the various agents steadily decreased.

After German reunification, it was decided by the German Federal Ministry for the Environment to save health data that were stored in different places, but which together formed the Wismut Health Data Archives. Based on parts of the information kept in different places by different bodies, a cohort of 64,311 former Wismut employees could be established. The objective of the cohort study was to examine the long-term health effects of chronic exposure to radiation, dust and arsenic as well as their combined effects. Particular focus should be given to the outcome lung cancer, but also to extrapulmonary cancers, cardiovascular and respiratory diseases.

This report gives a comprehensive overview on the background of the study, its objectives, material and methods employed so far for data analysis, information on how the cohort was established and which data are available, and descriptive results. All data referred to in this report are based on the cohort's second follow-up for the years 1946 – 2003.

MATERIAL AND METHODS

The total number of 64,311 eligible cohort members had to be reduced by 5,324 individuals, who did not fulfil the defined inclusion criteria (minimum employment time of 180 days, year of begin of employment between 1946 and 1989, year of birth after 1899, men only). Thus, the final cohort consists of 58,987 cohort members.

A first mortality follow-up was conducted until 31 December 1998 and a second until 31 December 2003, while at present the follow-up until 31 December 2008 has been started. The main sources for information on vital status were local registration offices. The main sources of information on causes of death were the Public Health Administrations and their corresponding archives or the pathology archive of the Wismut company. All causes of death are coded according to the 10th revision of the international classification of diseases (ICD-10).

For each cohort member detailed information on the job history is available, including information on begin and end of employment, work place (objects and shafts), job and working area (underground, processing/milling, open pit mining, surface) and times of absence of work.

The exposure to radiation was estimated retrospectively using a job-exposure matrix (JEM). For each work place and each type of job the JEM provided annual values of the exposures to radon and its progeny [Working Level Months, WLM], external

gamma radiation [mSv] and long-lived radio-nuclides [kBq·h/m^3]. A second JEM gave information on exposures to fine dust, silica dust and arsenic. These exposures were given in dust-years, where one dust-year is defined as an exposure to 1 mg/m^3 (for fine dust and silica dust) and 1 µg/m^3 (for arsenic), respectively, for 220 shifts of 8 hours each. Information on smoking is available for about 38% of the cohort members, but the quantity of information is poor and refers only to time periods after 1971.

Two statistical methods for risk analysis have been used so far, external comparisons with national mortality rates and internal regression methods. Standardised mortality ratios (SMR) were calculated with respect to overall mortality and mortality from malignant diseases based on comparisons with the general male population of East Germany of the same age over the same calendar period in the follow-up period 1960-2003. Internal analyses are performed by means of Poisson regression based on either categories of cumulative exposure or a linear relative risk model. The excess relative risk per unit of cumulative exposure was calculated, taking into account time, age and exposure rate effects.

DESCRIPTIVE RESULTS

A total of 35,294 (59.8%) cohort members were alive at 31 December 2003, 20,290 (35.5%) were deceased, and 2,773 (4.7%) were lost to follow-up. The cause of death was available for 19,588 (93.6%) of all deceased cohort members. Overall, a total of 7,395 deaths from cardiovascular diseases and 6,373 deaths from malignant cancers occurred, among them 3,016 lung cancers and 3,347 extrapulmonary cancers. Mean duration of follow-up was 35 years, comprising almost two million person-years of risk.

Around 86% of cohort members had been exposed to radiation at some time. Among the exposed, the mean cumulative exposure to radon and its progeny was 280 WLM (Maximum: 3,224 WLM), to external gamma radiation 47 mSv (Maximum: 909 mSv), and to long-lived radionuclides 4 kBqh/m^3 (Maximum: 132 kBqh/m^3). While the mean annual exposure levels for radon reached a maximum between 1954 and 1956, the highest levels of exposure to gamma radiation or long-lived radionuclides occurred between 1958 and 1966. Practically all cohort members had been exposed at some time to fine dust or quartz fine dust, with the highest levels occurring between 1948 and 1956. Only 18,234 individuals who had worked in specific mines in Saxony had been additionally exposed to arsenic dust.

STRENGTHS AND LIMITATIONS

The WISMUT cohort is the largest single cohort study on uranium miners world-wide. The main strengths of the study are, next to its size, the long follow-up period, the small percentage of lost-to follow-up, the large number of deaths from cancer, cardiovascular and respiratory diseases as well as the wide range of exposure to radon and its progeny, the availability of detailed information on other occupational risk factors such as external gamma radiation, long-lived radionuclides, fine dust, quartz fine dust and arsenic. Potential weaknesses of this study concern the accuracy of radiation exposure, particularly in the very early years of employment, the accuracy of causes of deaths, missing causes of deaths as well as missing information on potential confounders such as smoking, asbestos exposure, exposure to diesel fumes, etc.

2 INTRODUCTION

Developing the atomic bomb was probably the most secret enterprise of the 20th century. In 1939, the German chemist Otto Hahn announced the discovery of nuclear fusion, which he actually detected together with Lise Meitner. That was shortly before the Second World War. Further nuclear research was driven by the aim to develop an atomic weapon. The race was won by the USA, and in August 1945 two atomic bombs were dropped on Hiroshima and Nagasaki, respectively. The Soviet Union could make up this lead and its first nuclear bomb exploded in 1949 in the Kazakh steppes. This was mainly possible due to uranium mining in the Ore Mountains (Erzgebirge) in Saxony and Bohemia (Karlsch & Zbynek, 2003).

From 1946 – 1990, i.e. from shortly after the end of World War II and the rise of the cold war until the German reunification, there had been extensive uranium mining both in Saxony and Thuringia, which formed the southern parts of the former German Democratic Republic (GDR) (see Figure 2.1). Mining activities started in Saxony in the Ore Mountains. The first uranium mines in Czechoslovakia were also located in those mountains, just on the other side of the border. The mining in GDR was conducted by a Soviet, since 1954 by a Soviet-German Incorporated Company named Wismut (SAG/SDAG Wismut), while Wismut is the German name for the chemical element bismuth (Bi). It is estimated that about 400,000 persons may have worked in this time period with the company, most of them underground or in uranium ore processing facilities (Otten & Schulz, 1998). Until 1990 more than 5,000 of these workers have been compensated in the former GDR as radiation induced lung cancers. Until 1999, this number increased to 7,695 (Schröder et al., 2002). In 2004, the annual number of newly compensated cases was still almost 200 though with a decreasing trend (Koppisch et al., 2004).

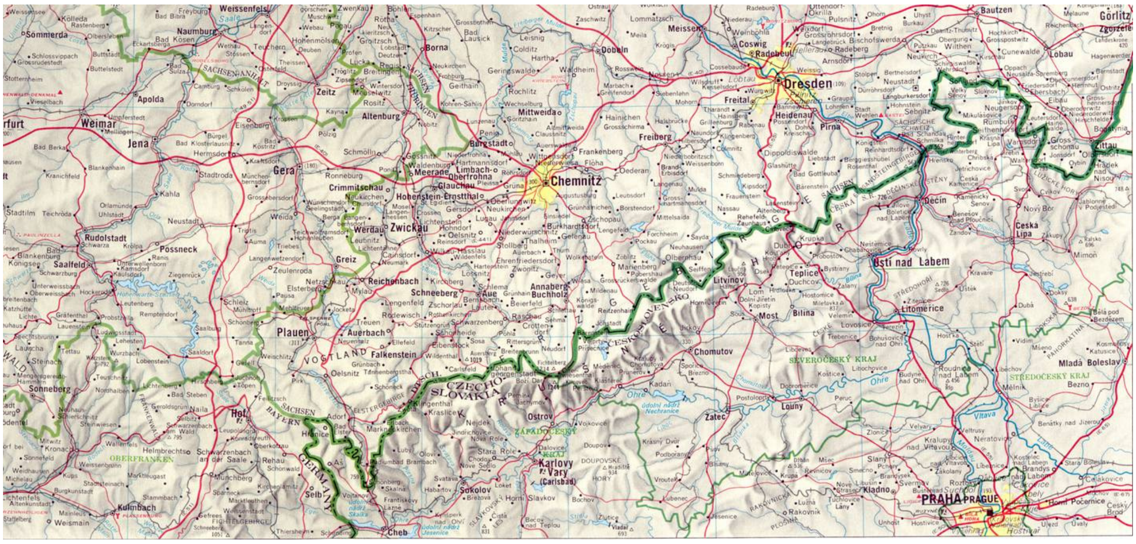

Figure 2-1: Map of the uranium mining area

After reunification, it was decided by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit / BMU) to save health data that were stored in different places, but which together formed the Wismut Health Data Archives (Gesundheitsdatenarchiv Wismut / GDAW), and which is now held by the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin / BAuA). These archives include paper files and histological material (Gille, 2004). The German Social Accident Insurance (Deutsche Gesetzliche Unfallversicherung / DGUV) keeps all those data which are relevant in the course of the compensation of occupational diseases. Payrolls are kept by the successor of the old Wismut Company, the Wismut GmbH. Based on parts of the information kept by any of these bodies, and with financial support from the BMU and the European Commission (contracts: FI4P-CT95-0031, FIGH-CT-1999-00013, and 516483 (FIP6)) a cohort of former Wismut employees could be established. The decision to do so was mainly driven by the perception that such a data set must not be destroyed or kept unused; both should be used for social-political manners and for scientific purposes.

An increased risk of lung cancer associated with exposure to radon and its progeny among underground miners is well established and has been summarised by the U.S. National Academies, Nuclear and Radiation Studies Board (formerly: Board on Radiation Effects Research), Committee on the Biological Effects of Ionizing Radiation (BEIR, 1999). Uncertainty, however, still remains with regard to the exposure-response relationship at low levels of radon exposure and other risk or effect modifying factors for lung cancer. Other uncertainties concern a possible relation of radon to extrapulmonary cancers, to diseases other than cancer and the effects of combined exposures such as radiation and arsenic or dust.

The aim of the German uranium miners study, which includes 58,987 former Wismut employees, is to evaluate the detrimental health effects associated with radiation, dust and arsenic. Particular focus will be given to the outcomes lung cancer, extra-pulmonary cancers, respiratory and cardiovascular diseases.

This report gives a comprehensive overview on

- the background of the study (Chapter 3)
- the objectives of the cohort study (Chapter 4)
- material and methods employed so far for data analysis, including information on how the cohort was established and which data are available (Chapter 5)
- descriptive results (Chapter 6)
- related studies, which are closely linked to the cohort (Chapter 7)
- all those persons and legal bodies which gave support to this study (Chapter 8)
- publications from the cohort study (Chapter 9).

All data referred to in this report are based on the cohort's second follow-up for the years 1946 – 2003. The team working on the cohort was advised by a working Group of the German Radiation Protection Commission (Strahlenschutzkommission – SSK), which was chaired by Prof. Lothar Kreienbrock.

3 BACKGROUND INFORMATION

3.1 History of mining in the Erzgebirge

The Ore Mountains of Saxony (Germany) and Bohemia (Czech Republic) have a long history of underground mining. As early as in the 12th century silver mining was performed, while later on other metals such as iron, bismuth, cobalt, nickel and tungsten and since the 20th century uranium were mined in the Schneeberg area.

In 1946, after the Second World War, the Soviet Union established the “Wismut” company, aiming to exploit uranium in Saxony, starting with reopened old silver mines. Later on mining was expanded to areas in Thuringia. During the operation period of the Wismut company (1946 to 1990) some 231,000 metric tons of uranium were produced (Wismut, 1999). Thus the former GDR became the third largest producer of uranium world-wide. With the German unification in 1990, mining was abandoned. Until today, minor amounts of uranium are produced as they become available from solution mining that was initiated before the German unification. The amount decreases constantly. In 2005, it were 77 tons (UIC, 2006).

The SAG/SDAG Wismut was organised by so-called objects (Objekte) which later were re-named to Mining Enterprises (Bergbaubetriebe). Each of the objects comprised a number of shafts, whereas the entire company has been constantly re-organised. Subsequently, new objects were opened while some closed, and shafts switched from one object to another. While the mining activities started in the old silver mining area, it spread out all over southern Saxony and Thuringia. In the later years, the most important Mining Enterprises were located in Thuringia. Next to that, open pit mining was introduced, and the company had its own milling and processing facilities.

Three time periods can be distinguished for the Wismut mining activities: the wild years, the time of transition, and the time of consolidation.

The "wild years" (1946 – 1954) are characterised by a large number of miners working at the same time and by a lack of occupational safety measures as well as radiation protection measures. Dry drilling was performed, leading to high dust exposure. Neither radiation measurements in general nor radon measurements in particular were conducted. Only natural ventilation took place, i.e. there was little air exchange. The major goal was uranium ore extraction. For the very early years, there were a high proportion of employees having been forced to work for the company. It is estimated that up to 50,000 people worked simultaneously for the mines (Otten & Schulz, 1998) and there were some 350 different mines. Based on rumours, a certain proportion of miners were female (Koepp, 1993). The number of accidents was high as well as attempts to flee from the mines, either by climbing over fences or by self-mutilation. Next to these events on an individual level, the old central part of Schlema collapsed due to tunnels too close to the surface. Here as in many other mining areas, settlements had to be given up due to the mining activities.

The "time of transition" (1955 – 1970) is characterised by a constant improvement of the working conditions. Wet drilling was introduced, leading to dust reduction, in the first phase of dust only, later of fine and ultra-fine dust, too. Radiation protection measures were introduced as well as radon area measurements at the work place. Next to that, forced ventilation was introduced leading to a much better air exchange underground. The number of miners was reduced to 20,000-40,000, and the number of mines to finally 90. The company changed from being an unpopular employer to a company favoured by its employees. This was, amongst other reasons, due to a good health system, good supply with provisions for the daily life, and good salaries.

During the "time of consolidation" (1971 – 1990) some 20,000 miners worked for the company in approximately 90 mines. Both, occupational and radiation protection reached international standards.

3.2 Socio-economic background of the Wismut company

The economic system in the emerging GDR was a socialistic one. In the Soviet zone of Germany, one quarter of the industrial capacity was controlled by Soviet companies (Rexin, 1982). The Wismut company, which was founded in 1945, was one of these. In the years following and in terms of mining companies, a distinction can be made between the nationally owned companies and the Soviet incorporated company. While the first were responsible for all types of mining except uranium, the latter was responsible only for uranium.

The mining company was the most important employer in the area. Not only mining activities were related to the company, but also the largest part of the infrastructure, namely in the Ore Mountains. This included a public transport system and commuting, wholesale and retail of goods for the daily life (namely food), and a health care system. Thus, the predominant role of the mining industry as an employer was not only directly linked to mining activities, but also indirectly.

In the early years of the Company, recruitment could be compulsory. So, prisoners of war were forced to work in the mines. Also, so-called volunteers had to sign contracts. This may be illustrated by the story of one miner, who talked to one of the Report's authors (B.G.): Back in 1946, the miner was working with a bakery when two armed persons entered the baker's. One of these two persons was from the Red Army, the other from the Police. They asked the owner of the bakery to nominate one of his two employees for working in the mines. The owner said that one of his two employees was married and had children, while the other was single. Thus, the other (i.e. the miner we talk about) had to sign a contract for working as a volunteer for six months in the mines. One part of the contract stated, that he is allowed to leave after six months given he could find another volunteer to take over his job. Otherwise, the contract is automatically prolonged for another six months. Since the miners lived in barracks and were fenced in, there was no contact to people outside and subsequently there was no chance to find a substitute. Thus, the miner's contract was prolonged several times. Finally, he said, after working and living conditions had improved, he didn't want to leave any more. So, he stayed until the mines were closed down.

Though Wismut was a huge enterprise, it was kept secret over a very long period of time. E.g., in a book of mining history in Germany, which was published in Western Germany, neither uranium mining nor the Wismut company is mentioned (Suhling, 1983).

3.3 Health effects from occupational radon exposure in mines

As early as in the medieval ages Georgius Agricola (Agricola, 1561) reported on a fatal lung disease among miners, which later on was called the "Schneeberg lung disease". Neither the disease's origin nor its diagnoses was clear, but the severity was obvious. Agricola mentioned women who were married to as much as seven husbands, of whom all were miners and died at young ages. The name of the disease was given after the city of Schneeberg, which was one of the mining centres at Agricola's time. It was not until the end of the 19th century, that the disease was recognised as being lung cancer (Härting & Hesse, 1879).

An increased risk of lung cancer associated with exposure to radon and its progeny among underground miners is well established and has been summarised by the Committee on the Biological Effects of Ionizing Radiation of the US National Research Council (BEIR, 1999). Uncertainty, however, still remains with regard to the dose-response relationship at low levels of radon exposure and other risk effect modifying factors for lung cancer. Other uncertainties concern a possible relation of radon to cancers other than the lung and the effects of combined exposures, e.g. radiation and arsenic, dust or tobacco smoke.

4 OBJECTIVES

The objective of the Wismut cohort study is to investigate the health effects associated with exposure to radiation, dust and arsenic. Table 4-1 shows the specific questions that had already been analysed and are published and a list of topics that are currently examined by the BfS and co-operation partners.

Table 4-1: Questions currently investigated by BfS

Outcome	**Follow-up period (# cases)**	**Risk factors considered**	**Status**	**Publication**
Lung cancer	1946 – 1998 (n = 2,388)	Radon exposure (*BEIR VI model*)	*Published*	*Grosche et al., Br J Cancer 2006*
Cardiovascular diseases	1946 – 1998 (n = 5,417)	Radiation exposure (Rn, LRN[1], Gamma)	*Published*	Kreuzer et al., Rad Env Biophys 2006
Extrapulmonary cancers	1960 – 2003 (n = 3,340)	Radon exposure	*Published*	*Kreuzer et al., Br J Cancer 2008*
Lung cancer	1946 – 2003 (n = 3,016)	Radon exposure (*Improved risk models*)	*Published*	*Walsh et al., Radiat Res 2010*
Cardiovascular diseases, Cancer	1946 – 2003	Radon exposure	*Published*	*Kreuzer et al. Rad Env Biophys, 2009c*
Lung cancer	1946 – 2003 (n = 3,016)	Combined effects of radiation, dust and arsenic	In preparation	Expected mid 2012
Cancer	1946 – 2003 (n = 6,373)	External gamma radiation (*Wismut vs. A-bomb study*)	In preparation	Expected mid 2012
Cardiovascular diseases	1946 – 2003 (n = 7,395)	Radiation and dust exposure	In preparation	Expected Dec 2011
Lung cancer histology	1946 – 2003 (n = 3,016)	Radiation organ dose	In preparation	Expected Mid 2012
Stomach	1946 – 2003 n = 595	Radiation organ dose (Rn, LRN, Gamma), dust, silica, arsenic	In preparation	Expected Dec 2011
Leukaemia	1946 – 2003 n = 128	Radiation organ dose (Rn, LRN, Gamma)	In preparation	Expected Mid 2011
Liver, Kidney	1946 – 2003 n = 159; 152	Radiation organ dose (Rn, LRN, Gamma), dust, silica, arsenic	In preparation	Expected Mid 2012

Extrathoracic Airways	1946 – 2003 n = 177	Radiation organ dose	In preparation	Expected Mid 2012
Prostate	1946 – 2003 n =264	Radiation organ dose	In preparation	Expected Mid 2012

[1] LRN: Long-lived radionuclides

Another aim is to lay the basis for national and international co-operation based on the cohort data, e.g. co-operation within the three European groups conducting the European uranium miners cohort studies (Czech Republic, France, and Germany) within the alpha-risk project funded by the EC under contracts FI4P-CT95-0031, FIGH-CT-1999-00013 and 516483 (FIP6).

Based on these activities, the results derived from the cohort study and its accompanying studies will improve today's knowledge on radiation and dust related risks. This knowledge may then be reflected in regulations on compensation and radiation protection.

5 MATERIALS AND METHODS

5.1 Definition of the cohort

Overall it is estimated that more than 400,000 workers may have been employed at the Wismut during its operation period. For about 130,000 workers sufficient information for a cohort study was available, i.e. information on job history and personal data (gender, name, date of birth, last known address). Based on this data a stratified random sample of 64,311 former employees was drawn. After excluding all individuals who did not fulfil the inclusion criteria for the cohort, the final cohort size comprised 58,987 individuals (see Figure 5.1-1). The following chapters describe in detail the procedures for constructing the cohort.

For data collection and for cohort stratification, BfS was advised by a group of experts, namely H.-E. Wichmann, I. Brüske-Hohlfeld, and M. Möhner (formerly at GSF Institute of Epidemiology, Oberschleissheim, Germany), E. Greiser (BIPS, Bremen, Germany) and R. Kusiak (Toronto, Canada). A pilot study for the cohort study was conducted by M. Blettner (DKFZ, Heidelberg, Germany) (Blettner et al., 1997).

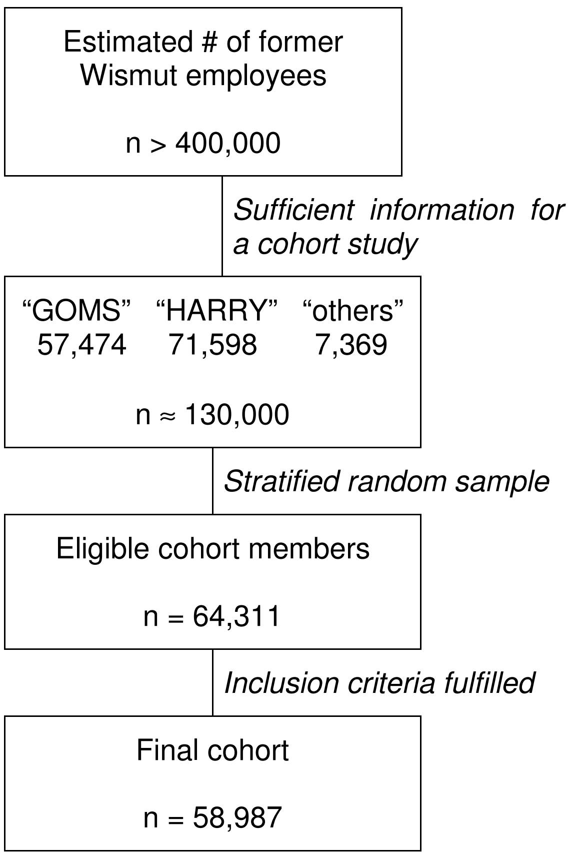

Figure 5.1-1: Procedure for selection of cohort members

5.1.1 First plans for the cohort

The 'Strahlenschutzkommission' (German Commission of Radiation Protection) decided in 1993 to establish a cohort of former Wismut workers. The cohort was planned to be restricted to 60,000 workers taken as a stratified random sample from approximately 130,000 persons having been employed between 1946 and 1989 and for whom sufficient information for a cohort analysis was available. In order to reflect the different mining conditions at the Wismut company, the sample should be stratified by the date of first employment (1946–1954, 1955–1970, 1971–1989), place of work (underground, milling/processing, surface), and area of mining (Saxony, Thuringia) because of different contents of arsenic in the two regions (Saxony having arsenic in the rock, Thuringia not). Since it was assumed that during the first years women also had worked for at least some time underground, it was planned to stratify the sample additionally by gender. Table 5.1.1-1 shows the plan for the composition of this stratified random sample. Figure 5.1.1-1 gives a schematic map of the mining areas and locations.

Table 5.1.1-1: Initial scheme for the composition of the stratified random sample of Wismut workers

Exposure status	Sub-cohort A (1946 – 1954)		Sub-cohort B (1955 – 1970)		Sub-cohort C (1971 – 1989)		
	Saxony	Thuringia	Saxony	Thuringia	Saxony	Thuringia	Σ
Underground:							
Men	15,000	0	6,000	10,000	3,000	5,000	39,000
Women	3,000	0	0	0	0	0	3,000
Non-exposed							
Men	4,000	0	2,000	4,000	1,000	2,000	13,000
Women	2,000	0	0	0	0	0	2,000
Milling/Processing	3,000 Men and Women						3,000
Σ	24,000	0	8,000	14,000	4,000	7,000	60,000

The *Deutsche Gesetzliche Unfallversicherung* (DGUV; German Statutory Accident Insurance) being responsible for the care of the former Wismut workers and thus having access to personal and occupational data was charged with the extraction of the data from the Wismut files by the BfS. The type of information which should be collected and the format of the data files were defined in a data catalogue.

In order to be able to draw the sample according to the above mentioned stratification scheme, information about year of first employment, location of working facility, gender and exposure status was necessary for every person eligible for the random sample. As this information had to be gathered first from the Wismut files, the set of workers from which the sample could be taken had to be restricted. For Saxony one mining facility being in operation for a particularly long time, called 'Objekt 09', was chosen, because a list of all workers ever employed in this 'Objekt 09' already existed. For these employees basic data, i.e. surname, first name, gender, date of birth, first and last date of employment, were extracted from the Wismut files by the *Zentrale Betreuungsstelle Wismut* (ZeBWis), a subsection of the DGUV, responsible for the medical care programme for former Wismut employees. Information whether a person had to be considered as exposed or unexposed or had worked in milling or processing facilities was available. The resulting data file, called 'GOMS', comprised data for

57,474 persons. In a similar way basic data were extracted from the Wismut files in an archive in Paitzdorf for all persons having worked in Thuringia and places in Saxony different from 'Object 09'. This file, called 'HARRY', consisted originally of data for 71,598 persons and has been complemented with data for another 7,369 persons in 1997.

Figure 5.1.1-1: Schematic map of mining locations in Saxony (Sachsen) and Thuringia (Thüringen)

5.1.2 Selection of the cohort members

For the selection of the cohort members all persons in the 'GOMS'- and the 'HARRY'-file have been numbered consecutively. These numbers were used for identifying the persons in the files. In the BfS the ID-numbers of those persons which should be included in the cohort were chosen and sent to DGUV for the extraction of the complete information needed according to the data catalogue from the Wismut files.

The main criterion for the selection of the cohort members was to fulfil the stratification scheme shown in Table 5.1.1-1. For the allocation of the subjects to the strata the following rules were laid down: i) Exposed workers were classified according to the beginning of exposure, not according to the start of Wismut employment. ii) Persons working underground less than 14 shifts per month, those being classified as 'bergmännisch i' and those working in surface mining are to be classified as 'exposed'. 'Bergmännisch i' was an internal job classification including persons who were not working as a miner, but were exposed to radiation (e.g. lorry driver). Additionally, the co-ordinators of the study decided in September 1994 that all women having worked in 'Objekt 09' underground or in Thuringia in milling or processing should be included in the cohort. Likewise, in 1995 all Wismut workers from 'Object 09' (i.e. those listed in the GOMS-file) belonging to sub-cohort B or C were determined to be cohort members.

In total, 64,773 ID-numbers have been sent to DGUV between middle of 1994 and August 1997 in 13 different files. During the course of data collection it was seen that only a very small proportion of the female cohort members had been exposed to radon. Thus, it was decided to stop collecting information about females but include more males, instead.

At the DGUV, where the data files have been prepared for delivery to BfS, data have been checked automatically for plausibility. At BfS again all data files received from DGUV have been checked for plausibility. Implausible or unclear data were returned to DGUV, where the data were re-examined and corrected if necessary. In order to check the quality of data extraction from Wismut files, data for 200 ID-numbers were collected a second time. The comparison between the two data files revealed some discrepancies, mainly in duration of employment and to a smaller extent in place of work. These results have been taken into consideration for the further extraction of information from the Wismut files, i.e. data have been updated, whenever new information regarding an individual cohort member was found.

5.1.3 Final inclusion criteria

A total of 64,311 eligible cohort members comprised the starting data base for the cohort study. The following inclusion criteria were defined:

- First employment between 1st January 1946 and 31st December 1989
- Minimum employment time of 180 days
- Year of birth after 1899
- Men only

All women (n=4,206) were excluded from the cohort study, because it turned out that only a very small number of women had worked underground. In addition all cohort members who were born before 1900 were excluded (n=799). A feasibility study for the follow-up had demonstrated that in this case a successful follow-up is nearly impossible *(Blettner et al., 1997)*. Further 260 persons had worked less than 180 days at the Wismut company or started working after 1989. A small number of 45 people were in the data set twice. Overall a total of 5,170 cohort members were excluded since they did not fulfil the inclusion criteria.

In addition 154 individuals had to be excluded because of implausible data or because WLM-Exposure was unknown. Thus the final cohort consists of 58,987 cohort members.

5.2 Mortality Follow-up

The first mortality follow-up determined the vital status of cohort members as of 31st December 1998. The follow-up was conducted by an external partner "NFO-Gesundheitsforschung" in Munich (Schroeder et al., 2002). Personal data on the first name, family name, year of birth and last known address were obtained from the original pay rolls of the Wismut Company. Information on the vital status and for deceased cohort members on the causes of death was obtained from several sources using the above mentioned personal data as starting base. The second mortality follow-up was conducted by the external partner "Mediveritas" in Munich (Toelg et al. 2006).

5.2.1 Vital status

With respect to the first mortality follow-up, the main source of information on the vital status was the local registration offices and corresponding archives. Other sources were the Pathology Archives of the Wismut company held by DKFZ at the time being (Wesch et al., 1999) and additional records on health data and occupational compensations of the former Wismut company.

- Local registration offices

  In a first step the local registration offices were contacted for information on the vital status. In Germany there are no central registries, but nearly each community has its own office. Based on the last known address, the corresponding registration offices were identified. They provided information whether a person is 1) still living at this address, 2) has moved to another known address or has moved without any information on the new address with specifying date of moving, 3) has died with specifying date of death and place of death or 4) could not be found. Since the date of information on the addresses was for the most part very old, this information was sometimes no longer stored in the local registries, but only in the corresponding former archives, so-called "Kreisarchive" (district archives). In this case the inquiries were sent to the corresponding archives. In total, 93.3% cohort members could be traced by this source of information.

- Pathology Archive

  A second source of information on the vital status was the Pathology Archive of the Wismut Company. In this archive more than 28,000 autopsy files of former Wismut employees and their relatives from the years up to 1990 are kept (Wesch et al., 1999; Wiethege et al., 1999). A record linkage of the cohort members with the Pathology Archives of the Wismut Company was performed in the beginning of 2000. In total 3,771 of the cohort members (6.4%) were identified in the Pathology Archives and information on the date of death was collected.

- Records of the Wismut company "ZeBWis"

  A third source of information were records of the former Wismut Company "ZeBWis" on health data, occupational compensations and so on. In total, 8.9% of the cohort members were identified as deceased by this source, in these cases only information on date of death was available.

For cohort members who could not be found by any of these sources and whose first address was completely unknown by the local registries, the payrolls and personal data were additionally sighted by the ZEBWIS to look for information on other additional addresses. This was done for about 2,000 cohort members, among them about one quarter was successfully traced in a next step by the local registration offices. Overall, in the first mortality follow-up a total of 3,148 people could not be traced by any of these sources, producing a loss-to-follow-up of 5.3 %.

During the 2nd mortality follow-up next to those being alive in the first follow-up, additional search was conducted on the 3,148 people that could not be traced within the first follow-up. Moreover, the vital status was corrected for a small number of cohort members, because it turned out that some people who had been classified as alive in the first follow-up were already deceased before 1998 based on information from the second follow-up. In addition, a few people had to be excluded from the cohort, because it turned out that they did not fulfil the inclusion criteria. Thus, the final cohort size differs between both follow-ups.

Table 5.2.1-1 gives information on the distribution of vital status and reasons for lost-to follow-up based on the 1st and 2nd mortality follow-up. The percentage of deceased cohort members increased from 28.1% to 35.5%, while the percentage of lost-to follow-up decreased from 5.3% to 4.7%. The main reason for lost to follow-up was that the cohort members could not be identified by any of the sources ("Person unknown"). In all other cases the person could be identified successfully under the last known address in the local offices, but they were lost to follow-up since they moved to a new unknown address, as refugee to former West Germany or to a foreign country. For a small percentage information was received that they were deceased, but the registries had no information on the year of death.

Table 5.2.1-1: Distribution of vital status and reasons for loss-to follow-up based on 1st and 2nd mortality follow-up

Vital status	by 31.12.1998 no.	%	by 31.12.2003 no.	%
Alive	39,255	66.5	35,294	59.8
Deceased	16,598	28.1	20,920	35.5
Lost to follow-up	3,148	5.3	2,773	4.7
deceased (unknown when)	67	0.1	28	0.1
moved (unknown where)	677	1.1	660	1.1
moved (to foreign country)	72	0.1	123	0.2
moved (refugee to former FRG)	427	0.7	401	0.7
Person unknown	1,905	3.3	1,561	2.6
Total	59,001	100.0	58,987	100.0

The lost to follow-up in the second follow-up was mainly related to year of birth and year of end of employment. It was especially difficult to trace persons with very old information on their residential address, e.g. old people or individuals who have stopped working with the Wismut company already in the 1950s (see Table 5.2.1-2 and 5.2.1-3).

Table 5.2.1-2: Distribution of vital status as of 31.12.2003 by year of end of employment

End of employ-ment	Alive		Deceased		Lost to FU		Total
	no.	%	no.	%	no.	%	no.
< 1955	804	29.5	1,439	52.9	476	17.5	2,719
1955–59	3,773	36.3	5,385	51.8	1,236	11.9	10,394
1960–64	1,792	36.9	2,818	58.0	247	5.1	4,857
1965–69	1,976	45.5	2,216	51.0	152	3.5	4,344
1970–74	1,760	40.9	2,412	56.1	131	3.0	4,303
1975–79	2,247	53.2	1,863	44.1	113	2.7	4,223
1980–84	2,788	62.9	1,534	34.6	110	2.5	4,432
1985–89	20,154	85.0	3,253	13.7	308	1.3	23,715
Total	35,294	59.8	20,920	35.5	2,773	4.7	58,987

Table 5.2.1-3: Distribution of vital status as of 31.12.2003 by year of birth

Year of birth	Alive		Deceased		Lost to FU		Total
	no	%	no	%	no	%	no
< 1905	1	0.1	876	86.0	142	13.9	1,019
1905–09	17	0.7	2,120	89.0	244	10.2	2,381
1910–14	125	3.5	3,124	88.7	274	7.8	3,523
1915–29	300	12.5	1,912	79.6	191	7.9	2,403
1920–24	1,133	26.4	2,918	68.0	239	5.6	4,290
1925–29	2,544	40.7	3,379	54.0	332	5.3	6,255
1930–34	4,541	56.8	3,013	37.7	440	5.5	7,994
1935–39	4,675	70.7	1,634	24.7	304	4.6	6,613
1940–44	3,161	79.9	705	17.8	89	2.3	3,955
1945–49	3,199	84.7	469	12.4	111	2.9	3,779
1950–54	3,815	89.3	352	8.2	103	2.4	4,270
1955–59	3,886	92.7	204	4.9	101	2.4	4,191
1960–64	3,863	94.4	123	3.0	107	2.6	4,093
1965–69	3,052	95.6	70	2.2	71	2.2	3,193
1970–74	982	95.5	21	2.0	25	2.4	1,028
Total	35,294	59.8	20,920	35.5	2,773	4.7	58,987

5.2.2 Causes of death

The main source of information on the causes of death was the Public Health Administrations and their corresponding archives, where copies of the death certificates were stored. Other sources were the Pathology Archives of the Wismut Company, where the autopsy files of former Wismut employees and their family members were kept, and the Wismut Health Data Archives (GDAW) located in Chemnitz.

- Public Health administrations

  In a first step the local public health administrations were asked for copies of the death certificates for deceased cohort members. Based on the place of death (for the years after 1970) or on the place of last residence (for the years before 1970) the corresponding public health offices were contacted. In total about 20,000 inquiries were sent to about 350 offices, which comprise about 60% of all offices in Germany. Unfortunately the compulsory period of record keeping differs from office to office, with periods of longest 30 years in areas in Saxony and Thuringia or only one year for example in Berlin. In cases, were the death certificate could not be found in the respective office and the place of death was either Thuringia or Saxony, we asked for support from the two central archives in these Federal States. For Saxony, death certificates were stored here for the years 1969 to 1990. For Thuringia, this accounts for the years 1969 to 1994. About two thirds of the missing death certificate was found in these two archives.

  Copies of the death certificates were sent to the BfS by the local Public Health Administrations or the corresponding archives by adding the identification number and withdrawing information on personal data of the cohort members according to the requirements of the German data protection standards. Based on these sources, information on the cause of death could be found for about 80% of all deceased cohort members.

- Pathology Archive

  Further sources of information were the autopsy files of the Pathology Archives of the Wismut Company. As stated before, this information was available for 3,771 cohort members.

- Wismut Health Data Archives (GDAW)

  A third source was the health data base of the Wismut company (GDAW, Gesundheitsdatenarchiv). A record linkage was performed for a sub-sample of deceased persons without any information on cause of death from both other sources. For about 50% of these persons information on the cause of death was successfully traced. It was mainly based on autopsy.

In the first follow-up for a total of 1,952 deceased persons the cause of death was not available. Two strategies had been followed to get further information on cause of death for these persons: First, a record linkage with the Wismut Health Data Archives was performed. Second, for those who died after 1985 the complete follow-up was repeated within the second follow-up, because it was assumed that causes of death are missing due to wrongly identified persons or typing errors in the procedure of follow-up. Based on these procedures, the percentage of missing causes of death could be greatly improved in the second follow-up (6.4 %) compared to the first follow-up (11.8 %) (see Table 5.2.2-1).

Table 5.2.2.-1: Availability of information on cause of death (COD) and reasons for missing COD's

Mortality follow-up ending on	31.12.1998 no.	31.12.1998 %	31.12.2003 no.	31.12.2003 %
Total number of deceased people	16,598	100.0	20,920	100.0
COD available	14,646	88.2	19,588	93.6
COD not available	1,952	11.8	1,332	6.4
Deceased in foreign country	24	0.1	42	0.2
Deceased in Berlin	60	0.4	130	0.6
No information on place of death	446	2.7	48	0.2
No exact information on date of death	35	0.2	55	0.3
Death certificates destroyed, no longer stored, other reasons	1,387	8.4	1,057	5.1

The main reasons for missing causes of deaths were that the death certificates were no longer stored. Another particular problem concerns people who died in Berlin, because death certificates were stored only for one year. Overall there is only a small percentage of deceased people who died in foreign countries.

Table 5.2.2-2 shows that the availability of causes of death was related to year of death. Particularly for those who died before 1970 it was difficult to get a copy of the death certificate.

Table 5.2.2.-2: Availability of information on cause of death by year of death

	Mortality follow up ending on			
	31.12.1998		31.12.2003	
Year of death	no.	COD available	no.	COD available
< 1970	1,479	50.6 %	1,560	58.8 %
1970 – 1979	3,132	90.0 %	3,255	95.1 %
1980 – 1989	5,368	91.4 %	5,554	96.7 %
1990 – 1999	6,619	93.3 %	7,538	96.7 %
2000 – 2003	-	-	3,013	96.9 %
Total	16,598	88.2 %	20,920	93.6 %

All causes of death from any of the different sources were coded according to the 10th revision of the International Classification of Diseases (Deutsches Institut für medizinische Dokumentation und Information DIMDI, 2004). This was done by trained coding staff at the Statistisches Landesamt of Rheinland-Pfalz. Coding was performed for the clinical diagnosis and – if available – also for the diagnosis based on autopsy.

In order to check for errors in coding, a sub-sample of 750 death certificates was coded a second time by the same office as well as by another authorized coding office (Bayerisches Statistisches Landesamt). About 10% of the coding differed by main group (1-digit code of the ICD-code) or by site of tumor (3-digit code). It was therefore decided that a physician at the BfS (A. Tschense) additionally controlled all codings. In the case of errors or inconsistencies death certificates were sent again to the coder in order to clarify the situation. Remaining inconsistencies were decided by an external expert. A double data entering of all coded causes of death was performed in order to avoid typing errors.

For all analyses the diagnosis based on autopsy and only if not available the clinical diagnose was used.

5.3 Job histories

The job histories of the Wismut employees provide information about exact date of begin and end of employment, work place (objects and shafts), job (4-digit code) and a so called ‘classification’ which indicates if a person had worked underground, in processing or milling, open pit mining or on surface. Every change of a person’s work place or job or classification gives a new row of data. There were two classifications ‘underground’, the first one (classification 1) was taken when the person had worked more than 50%, the second (classification 5) when the person had worked 50% or less underground of the working time. In the latter case additional information on the number of underground shifts a person worked was given in a separate data file. This additional file also provided information about any times of absence of work. For 11,521 cohort members such underground shifts are documented (in terms of days per year) and for 23,923 individuals absent times are documented (in terms of months per year).

An example of the job histories of the person with the ID number 52 is given in Tables 5.3-1 and 5.3-2, where code 1 in the additional file (see Table 5.3-2) stands for absent times (time in months) and code 2 for underground shifts (time in days).

Table 5.3-1: Main File of Job Histories (Example for worker with ID number 52)

Number	Begin	End	Code for place of work	Code for job type	Classification of area of work [1]
52	1963/11/01	1964/01/31	009 000 000	7427	5
52	1964/02/01	1964/05/31	009 000 000	7427	1
52	1964/06/01	1964/07/31	009 000 000	7427	5
52	1964/08/01	1964/08/31	009 000 000	7427	1
52	1964/09/01	1964/09/30	009 000 000	7427	5
52	1964/10/01	1964/12/31	009 000 000	7427	1
52	1965/01/01	1965/04/30	009 000 000	7427	5
52	1965/05/01	1965/07/09	009 000 000	7427	1
52	1965/07/10	1967/12/31	009 366 000	1000	1

[1)] Code 1: > 50% of the working time underground, 5: ≤ 50% of the working time underground

Table 5.3-2: Additional File of Shifts and Absent Times

Number	Year	Code	Time
52	1964	2	24
52	1965	2	19
52	1967	1	1

5.4 Exposure to Radiation

5.4.1 Job-Exposure-Matrix

The exposure to radiation was estimated retrospectively using a job-exposure matrix (JEM), which was developed by the Miners' Occupational Compensation Board (Bergbau-Berufsgenossenschaft, BBG) in Gera (Lehmann, 2004; Lehmann et al., 1998). For each work place (object, shaft) and each type of job the JEM provides annual values of the exposures to radon and its progeny [WLM], external gamma radiation [mSv] and long-lived radionuclides [kBq·h/m^3] covering the whole operating time of the Wismut company from 1946 to 1989. Exposure to radon and its progeny is expressed in Working Level Months (WLM). A working level (WL) is defined as 1.3×10^5 MeV of alpha energy/l air which will be emitted by short lived radon progeny. A working level month equals exposure to 1 WL for 170 hours.

Since there were no radon measurements available before 1955, the exposure was estimated retrospectively for this time period from data e.g. on the yearly production of ore, its uranium content, shaft geometry, techniques of uranium ore production and ventilation. The representativeness of the first measurements of the Wismut Company was verified on the basis of radon measurements in the mines of Schneeberg and St.Joachimsthal (today's Jachimov in the Czech Republic) in the time period from 1937 to 1945 and the measurements of the Czech uranium mines, which are available since 1949. Individual measurements were not available before 1971. Table 5.4.1-1 outlines the exposure measurements performed by the Wismut Company during the different time periods.

Table 5.4.1-1: Exposure Measurements (Lehmann et al. 1998, p. 24)

Year	Measurement
Until 1954	No measurements
From 1955	Partial measurements of gamma exposure rates in a few objects
1955 – 1965	Partial measurements of radon in a few objects
1964 – 1965	Partial measurements of radon progeny (RnFP)
From 1966	Regular measurements of radon and its progeny
From 1967	Measurements of long-lived radionuclides (LRN)
From 1971	Individual monitoring of exposure

5.4.2 Evaluation of the work place

The mines of the Wismut Company were organised into different objects with several shafts within one object. Originally the JEM was developed object oriented, i.e. exposure estimates were based on the highest possible exposure in the respective object (Lehmann et al., 1998). This was primarily done to assure conservative estimates for compensation purposes. In order to get more realistic exposure estimates for scientific purposes calculations were based on shafts rather than on objects, since shafts represent the actual geological situation of a work place by far better than objects do (Lehmann, 2004). Furthermore shafts quite often were reorganised under different objects, and therefore an object based calculation alone would have led to worse or wrong estimates.

In this way annual exposures in WLM were established for 35 mining facilities (19 mining (Gewinnung), 6 adjustment (Ausrichtung), 10 exploration (Erkundung), 11 open pit mining facilities (Tagebau), 21 processing and milling facilities (9 processing, 7 radiometric automatic sorting/radiometric processing factories), 5 sampling works (Beprobungszechen)). Table 5.4.2-1 gives the range of the exposures per year in the various areas of operation for exposed persons (underground/processing and milling) and persons working on the surface, respectively. Maximum annual exposures were estimated for underground miners with 355 WLM in Saxony and 375 WLM in Thuringia.

The final object-/shaft conversion table consists of 377 items altogether.

Table 5.4.2 -1: Range of annual exposures by work place

	RnP [WLM]	LRN [kBqh/m^3]	Gamma [mSv]
Saxony (Underground)	1–355	>0–17.2	>0–128
Saxony (Surface)	>0–2	>0–0.8	>0–10.8
Thuringia (Underground)	1–375	>0–4.2	>0–9.5
Thuringia (Surface)	>0–1	>0–1	>0–4.8
Königstein (Underground) [1]	0.1–40	>0–1.6	>0–12.7
Königstein (Surface)	>0–0.5	>0–0.2	>0–2.4
Processing/Milling	0.9–7.4	0.6–28.8	3–7.7
RAS/RAF	0.5–2.2	0.1–0.3	9.2–21.7
Sampling Works	2.2–15.4	0.2–10.8	18.3–72.4
Open Pit Mining	0.1–6.0	>0–2.2	>0–13.5
Not exposed	0	0	0

[1] *In Königstein solution mining was performed*

5.4.3 Evaluation of the jobs

Altogether 981 jobs within the above mentioned facilities were evaluated introducing a so called 'job factor' (with a range of 0 – 1) which actually was a weighting factor to the exposure of a hewer (Hauer) with the job factor 1. For processing and milling facilities the estimations are based on the various steps of processing and the directly related jobs. Thus by means of the JEM individual exposures for each employee of the Wismut company can be estimated.

In order to calculate the exposures of cohorts with the JEM, the German Social (Hauptverband der gewerblichen Berufsgenossenschaften, DGUV) developed special software together with the Miners's Occupational compensation Board (Bergbauberufs-genossenschaften, BBG). The latest revised version of the programme was available in August 2005.

5.4.4 Software for calculating exposure estimates

The software computes both annual and cumulative exposures for every person of the cohort which is carried out in the following successive steps: a) conversion of codes, b) estimation of underground shifts, c) a raw and d) the final calculation.

The calculation software is preceded by a code conversion (a) as the JEM is based on different codes both for work places and jobs as they were used by the DGUV. Thus special code conversion software had to be developed which has to be run before the actual exposure calculation. This code conversion had turned out to be a very difficult and labour intensive job, in which people were involved who knew about the various relations of the objects and shafts of the Wismut company for all the years passed. Altogether 809 DGUV codes of objects and shafts were reduced to 277 BBG codes, while 745 DGUV job codes increased to 820 BBG codes, based on our cohort data.

The following DGUV data were not converted, and accordingly not calculated:

- Times of employment after 31st December 1989
- Times of employment without pay records
- Job key 9996 'No productive job' (all at the surface)
- Job key 9998 'No Wismut job'
- Job key 9999 'No information'
- Object key 000 000 000:

In the next step of the calculation software (b) more than 20 % of all documented underground shifts had to be estimated as there was no information in the additional file on the number of shifts the persons had worked. Before 1957 underground shifts had not been documented at all. For almost 3,500 persons of the cohort shifts were estimated that way.

The third step (c) was a raw calculation ignoring underground shifts and times of absence. For persons who had worked 50 % or less underground the JEM surface values were used in this stage of the calculation software. The individual exposures were calculated by multiplying the appropriate annual exposure value (from the JEM) with the job factor and the days per year a person had actually worked. Then underground shifts (both the documented and the estimated ones) and times of absence were calculated. In the final step (d) the underground shifts were added and times of absence were subtracted from the raw exposures. Additionally to the exposures of radon and its progeny, long-lived radionuclides and external gamma radiation, radon equivalent values (Jacobi, 1999) for the lung were calculated.

5.5 Exposure to fine dust, silica dust and arsenic

Based on a report on exposures other than radiation (Bauer 2000), a job-exposure matrix was developed by DGUV. This exposure matrix gives exposure estimates for dust, silica dust and arsenic. The exposures are given in dust-years, where one dust-year is defined as an exposure to 1 mg/m^3 (for dust and silica dust) and 1 µg/m^3 (for arsenic) over a time period of 220 shifts of 8 hours each, respectively.

A software was developed by BBG which is working in the same way as the radiation programme works (conversion of codes, estimation of underground shifts and absent times, raw and the final calculation of exposure estimates). While the software computes both annual and cumulative exposures to dust and silica dust for every person of the cohort annual and cumulative exposures to arsenic are only calculated for cohort members who worked in areas with rock containing a sufficient concentration of arsenic. The threshold value for arsenic was defined as 10 µg/m^3 air (inhaled particle fraction) and exposures below this value were considered as irrelevant. As arsenic exposure measurements have been extremely rare, a direct access to those data was not possible. Consequently, the arsenic content in the deposit and the data on inhalable dust exposure were used instead. In cases where the arsenic content was found to be below 100 mg/kg rock, this component was disregarded completely, as at concentrations of 100 mg/kg, even at the highest inhalable dust exposures, the exclusion criteria of 10 µg/m^3 was not reached. Persons with no exposure calculations for arsenic were set to zero in the analyses (Dahmann et al. 2008)

5.6 Smoking

The sources of information are records filled in during the regular medical examinations every employee had to undergo. This information refers almost only to the years after 1970. Smoking habits were recorded according to self-reported consumption. It includes the following:

- non-smoker
- cigarette smoker
- smoker of other products (i.e. cigars or pipe tobacco)

The coding of the smoking habits was performed on the basis of the following coding table which was part of the annual medical examinations:
0 – non-smoker
1 – non-smoker since 1 year at least
2 – occasional smoker
3 – pipe or cigar only
4 – cigarettes (< 5 years or < 10 cigarettes/day)
5 – cigarettes (5 years and more or 10 cigarettes/day and more)
9 – no information available.

At least some information on smoking is available for about 38% of the cohort members. Table 5.6-1 gives the number and percentage of employees - subdivided by sub-cohorts - for which at least one smoking information is available. For almost two thirds (64%) of the cohort members in sub-cohort C – where first day of employment was January 1, 1971 or later – information on smoking is available. However, this information is very rough.

Table 5.6-1: Employees by sub-cohort and information on smoking

Sub-cohort by begin of employment	Employees	% with smoking information
1945–54	23,917	22,4 %
1955–70	17,950	34,3 %
1971–89	17,134	64,4 %
All	59,001	38,2 %

5.7 Statistical methods

Two statistical methods were used, external comparisons with national mortality rates (Kreuzer et al., 2008) and internal analyses based on Poisson regression (Grosche et al., 2006; Kreuzer et al. 2006, 2008). The number of years at risk for each miner is calculated as the time between entry into and exit from the cohort. Date of entry is defined as start of employment plus 180 days (inclusion criteria). The date of exit is defined as the earliest of date of death, emigration, loss to follow-up, or the end of the period of follow-up.

5.7.1 SMR analysis

With respect to external analyses, the mortality rates observed in the cohort were compared with those of the general male population in Eastern Germany, formerly the German Democratic Republic. External rates were only available from 1960 onwards. For this reason, all analyses were limited to the follow-up period 1960 to 2003 and a total of 236 cohort deaths prior to 1960, were excluded (Kreuzer et al., 2008).

The expected mortality rate was calculated by applying national mortality rates, grouped by calendar year and 5-year age bins, to the number of person-years corresponding to the grouped cohort data. The Standardized Mortality Ratio (SMR) is given by the ratio of O/E, where O is the number of observed deaths in the cohort, and E is the number expected from external rates. A 5-year lag was used in calculating the cumulative exposure to radon for all sites of cancer other than leukemia and a zero lag for leukemia. In order to test the significance of the SMR, associated confidence intervals were constructed by assuming that the observed number of deaths, O, is approximately Poisson distributed and applying the method of Breslow and Day (1987).

The SMR's were corrected for missing causes of death by dividing O by the proportion of causes of death that are known, p, which is Binomial distributed. In practice it was found to be adequate to ignore the variability of p since, when methods were applied to account for this variability (Rittgen and Becker, 2000), the resulting SMR confidence intervals were not significantly affected.

Causes of death in the reference population had been coded in different classification systems for different time periods depending on the source of the data. Table 5.7.1-1 shows the data sources and classification systems used. For the analyses all diagnoses have been transformed to ICD 10-Codes.

Table 5.7.1-1: Data Sources and classification systems for causes of death in the reference population.

Time Period	Data Source	Classification System
1960–1967	Bundesarchiv	GDR-Classification System
1968–1973	Bundesarchiv	ICD 8
1974	Bundesarchiv/WHO	ICD 8/ICD 9
1975–1978	Bundesarchiv	ICD 8
1979	Bundesarchiv/RKI	ICD 8/ ICD 9
1980–1979	Federal Statistical Office	ICD 9
1998–2003	Federal Statistical Office	ICD 10

5.7.2 Internal analysis

Internal analyses are performed in terms of maximum likelihood computations of the dose, time, and age dependence of excess tumour rates among the exposed populations.

In the case of acute radiation exposures, one can use comparatively simple models for risk modelling. The major analyses have utilized relations that are special cases of the *relative risk model*:

$$\lambda(a,D) = \lambda_0(a) \cdot \left(1 + f(e) \cdot g(a) \cdot h(t) \cdot u(D)\right) \qquad (1)$$

In this relation $\lambda(a,D)$ stands for the cancer mortality (or incidence) rate at age attained, *a*, after a radiation dose, *D*, received at age *e*. The age specific baseline rate is $\lambda_0(a)$. The variable *t=a-e* is the time since exposure. Other variables, such as sex, or confounders, such as smoking, may be accounted for, although they are not noted here.

In the analysis of the lung cancer mortality among underground miners exposed to radon and radon progenies one deals with continuous exposures and, accordingly, one needs to consider integrals over the exposure rate, *c*(*e*), in its dependence on age *e*[*)]. A model has been used for this purpose by the BEIR VI- committee (BEIR 1999) that contains the two functions *g*(*a*) and *h*(*t*):

$$\lambda(a) = \lambda_0(a) \cdot \left(1 + g(a) \cdot \int h(a-e) \cdot c(e) de\right). \qquad (2)$$

The dependences *f*(*e*), *g*(*a*), and *h*(*t*) are often taken to be step functions, but one can equally use analytical expressions. Regardless of the approach that is chosen, *f*(*e*) and *g*(*a*) are found to be decreasing functions of *e* and *a*. The subsequent treatment is independent of the type of the functions *f*(*e*), *g*(*a*), and *h*(*t*) that are chosen. A more general notation will, therefore, be used for the relative risk model:

$$\lambda(a) = \lambda_0(a) \cdot \left(1 + \int f(e, a-e) \cdot c(e) de\right) \qquad (3)$$

This includes Eqs (1) and (2) as special cases, and it can, of course, equally be written as an absolute risk model. Linearity in dose is assumed, because it is the most commonly invoked condition.

5.7.2.1 Equations for the likelihood

[*)] The term *exposure rate* is here used instead of *dose rate*. The reason is, that the case of chronic exposure relates mostly to the radon studies, where one refers to the exposure (in the unit WLM) rather than to absorbed dose. The age is, in the subsequent equations, treated as a continuous variable, and the exposure rate is denoted by *c*(*e*). In the parts of the article that relate to the actual numerical evaluations the exposure in the specified year of age is required; it is denoted by *C*(*e*).

After choosing a model one determines those numerical values of its parameters that fit a data set best in terms of the maximum likelihood. The computations involve multiple evaluations of the likelihood and its derivatives with respect to the model parameters. The most direct approach is a *person-by-person* calculation of the likelihood that uses the individual age information and the individually assigned dose values. Fast computers tend to make computing times irrelevant, but it can, nevertheless, be inconvenient to perform a person-by-person regression in a large cohort. It is, therefore, usual to categorize the variables *a, e, t,* and the exposure *c*(*e*) and, thereby, to group the data from the epidemiological follow-up into a finite number of ´cells´. The likelihood is then computed in terms of the Poisson statistics, and this *cell-by-cell* calculation can reduce considerably the number of computational steps in the determination of the maximum likelihood.

In the Poisson regression the total likelihood is the product of terms for the individual cells (*j,k,l*), which correspond to the variables e_j, t_k, C_l:

$$L = \sum_{j,k,l,} \exp(-m_{j,k,l}) \cdot (m_{j,k,l})^{\nu_{j,k,,l}} \Big/ \nu_{j,k,l}\,! \tag{4}$$

where $\nu_{j,k,l}$ is the observed number of cases, while $m_{j,k,l}$ is the expected number of cases in the cell:

$$m_{j,k,l} = \lambda_{j,k,l} \cdot py_{j,k,l} \tag{5}$$

$py_{j,k,l}$ is the number of person years, and $\lambda_{j,k,l}$ is the tumour rate specified by the model (see eq. (3)).

In the log-likelihood one disregards the constant term ($\nu_{j,i,k}$!).

$$\ln(L) = \sum_{j,k,l,} \nu_{j,k,l} \cdot \ln(m_{j,k,l}) - m_{j,k,l} \tag{6}$$

The deviance *Dv* is twice the difference of the log-likelihood and the log-likelihood of the fully saturated model ln (L^*):

$$Dv = 2 \cdot \{ \ln(L^*) - \ln(L) \} \tag{7}$$

with $\ln(L^*) = \nu_{j,k,l} \cdot ln(\nu_{j,k,l}) - \nu_{j,k,l}$ (8)

The explicit formula of the deviance in the cell (*j,k,l*) to be maximized is then:

$$Dv_{j,k,l} = 2 \cdot \left\{ \nu_{j,k,l} \cdot \ln\left(\frac{\nu_{j,k,l}}{m_{j,k,l}}\right) - \nu_{j,k,l} + m_{j,k,l} \right\} \tag{9}$$

5.7.2.2 Estimation of background rates

In the analysis of radiation-related excess lung cancer rates, the quantification of background rates is of major importance. For this purpose one can use external rates, such as national statistics, however it remains uncertain whether the background mortality of a specific cohort is then adequately described. National statistics relate to a large, divergent country and may in addition be of uncertain accuracy.

Therefore an internal estimate of the background lung cancer rate, $\lambda_0(a)$, has been employed in the present analysis. Two alternative approaches were taken and compared: The background rate was estimated non-parametrically by means of stratification, and it was modelled parametrically using analytical functions. Different parametric approaches led to almost identical results. Thus a comparatively simple analytical expression with three free parameters was selected (age *a* given in years):

$$\lambda_0(a) = \exp\left(k + c_1 \cdot (a-60) + c_2 \cdot (a-60)^2\right) \quad (11)$$

The results on lung cancer risk have been published (Grosche et al., 2006).

5.8 Data protection within the cohort study

The cohort study is based on individual data, including name, date of birth, and last known address. According to data protection regulations, the individual data are only used for follow-up purposes. They are kept separated from those data which are important for the scientific evaluation of the data set, e.g. exposure data. Each cohort member has an individual identifier, the so-called Stichprobennummer, which resulted from the selection of cohort members (see Chapter 5.1.2).

Individual data are kept in a locked room in a locked cupboard. A file with identifying data is kept on a stand-alone computer, which is not connected to BfS' network, while the file itself is protected by a password. One copy of this file is in the above mentioned locked cupboard, a second copy is held by BfS' data protection officer.

For information exchange between those three institutions mostly involved in the Wismut related medical after-care and research, an exchange file was constructed. This file allows a specific inquiry for selected information on specified individuals being part of one of the three institutions' groups looked after. This file will allow for rapid information exchange without violating data protection rules. And it will avoid unnecessary enquiries at local authorities. The three institutions are Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal Office for Occupational Safety and Health), where the file is maintained and which is in charge of the Gesundheitsdatenarchiv Wismut (Wismut Health Archive), the Deutsche Gesetzliche Unfallversicherung / DGUV (German Statutory Accident Insurance), where the medical after-care is coordinated, and the Bundesamt für Strahlenschutz (Federal Office for Radiation Protection), where the cohort study is conducted.

6 RESULTS

This chapter provides descriptive information on basic characteristics of the cohort, exposure to radiation, dust and arsenic, and health data based on data of the second mortality follow-up by 2003. In order to reflect the different mining conditions of the Wismut company operation, most of the results are presented stratified by year of first employment. Of the overall 58,987 cohort members, 23,920 started working with the Wismut company in the years between 1946 and 1954 (sub-cohort A), 17,944 between 1955 and 1970 (sub-cohort B), and 17,123 after 1970 (sub-cohort C).

6.1 Basic characteristics of the cohort

The distribution of the year of birth by sub-cohort is given in Table 6.1-1. The most frequent years of birth were between 1925 and 1939. It clearly differs between the sub-cohorts. More than 90% of sub-cohort C was born after 1950, while all men of sub-cohort A were born before 1945.

Table 6.1-1: Distribution of year of birth by begin of employment (sub-cohort)

Year of birth	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
< 1905	804	3.4	213	1.2	2	0.0	1,019	1.7
1905–09	2,061	8.6	316	1.8	4	0.0	2,381	4.0
1910–14	3,069	12.8	450	2.5	4	0.0	3,523	6.0
1915–19	2,064	8.6	336	1.9	3	0.0	2,403	4.1
1920–24	3,642	15.2	642	3.6	6	0.0	4,290	7.3
1925–29	5,264	22.0	964	5.4	27	0.2	6,255	10.6
1930–34	5,684	23.8	2,228	12.4	82	0.5	7,994	13.6
1935–39	1,331	5.6	5,035	28.1	247	1.4	6,613	11.2
1940–44	1	0.0	3,501	19.5	453	2.6	3,955	6.7
1945–49	-	-	2,862	15.9	917	5.4	3,779	6.4
1950–54	-	-	1,377	7.7	2,893	16.9	4,270	7.2
1955–59	-	-	20	0.1	4,171	24.4	4,191	7.1
1960–64	-	-	-	-	4,093	23.9	4,093	6.9
1965–69	-	-	-	-	3,193	18.6	3,193	5.4
1970–74	-	-	-	-	1,028	6.0	1,028	1.7
Total	23,920	100.0	17,944	100.0	17,123	100.0	58,987	100.0

Table 6.1-2 shows the distribution of the year of end of employment by sub-cohort. Overall, about 40% of the cohort members were still employed after 1985.

Table 6.1-2: Distribution of the year of end of employment by sub-cohort

Year of end of employment	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
< 1954	2,719	11.4	-	-	-	-	2,719	4.6
1955–59	7,263	30.4	3,131	17.4	-	-	10,394	17.6
1960–64	3,267	13.7	1,590	8.9	-	-	4,857	8.2
1965–69	1,934	8.1	2,410	13.4	-	-	4,344	7.4
1970–74	2,019	8.4	1,970	11.0	314	1.8	4,303	7.3
1975–79	1,552	6.5	1,237	6.9	1,434	8.4	4,223	7.2
1980–84	1,366	5.7	1,018	5.7	2,048	12.0	4,432	7.5
1985–89	3,800	15.9	6,588	36.7	13,327	77.8	23,715	40.2
Total	23,920	100.0	17,944	100.0	17,123	100.0	58,987	100.0

Overall the mean age at begin of employment was 24 years. It was higher for those in sub-cohort A (27 years) than for those in sub-cohorts B (24 years) and C (21 years). The youngest one was 13 years, when he started to work with the company, the oldest one 68 years, respectively. Table 6.1-3 shows the distribution of age at begin of employment in 5-year categories by sub-cohort. It completely differs between the sub-cohorts. Nearly 60% of all cohort-members of sub-cohort C started in very young ages (below 20 years) to working with the company compared to less than 30% in sub-cohort A.

Table 6.1-3: Distribution of age at begin of employment by sub-cohort

Age at begin of employment	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
10–14	135	0.6	343	1.9	11	0.1	489	0.8
15–19	6,613	27.6	6,937	38.7	9,942	58.1	23,492	39.8
20–24	5,382	22.5	5,776	32.2	4,488	26.2	15,646	26.5
25–29	3,572	14.9	2,213	12.3	1,507	8.8	7,292	12.4
30–34	2,441	10.2	978	5.5	677	4.0	4,096	6.9
35–39	2,982	12.5	499	2.8	298	1.7	3,779	6.4
40–44	1,864	7.8	479	2.7	124	0.7	2,467	4.2
45–49	816	3.4	327	1.8	42	0.2	1,185	2.0
50–54	115	0.5	245	1.4	19	0.1	379	0.6
55–59	-	-	112	0.6	5	0.0	117	0.2
60+	-	-	35	0.2	10	0.1	45	0.1
Total	23,920	100.0	17,944	100.0	17,123	100.0	58,987	100.0

Table 6.1-4 provides information where the men had worked. A total of 67.3% of them have worked underground and not in processing or milling facilities or in open pit mining factories. About 7.5% worked in processing or milling facilities only; 2.2% in open pit mining factories, only, and 15.8 % worked on the surface only. About 88% of the latter were not radon exposed, while 12% received some radon exposure. The remaining employees (7.5%) had mixed places of work. Instead of subdividing workers by place of work, another possibility is to consider the distribution of employment years by place of work. In this case, 53% of the employment years were spent underground, 6.9% in processing milling, 1.1% in open pit mining and 38% at surface.

Table 6.1-4: Wismut employees by work place

Work place	%	% exposed to radon
Underground only	67.3	100.0
Processing/Milling incl. Bergmännisch "i" only	7.5	100.0
Open pit mining only	2.2	100.0
Surface only	15.8	11.7
Mixed	7.5	100.0
All	100.0	86.1

Table 6.1-5 shows the distribution of duration of follow-up in years. Members of sub-cohort A were followed on average 40 years, summing up to 946,930 person-years. Members of sub-cohort B were followed on average 37 years and those of sub-cohort C 23 years. Overall, the mean duration of follow-up was 34 years, summing up to 1,997,041 person-years.

Table 6.1-5: Distribution of duration of follow-up in years by begin of employment

Sub-cohort	no.	Min	Max	Mean	Median	Sum
1945–54	23,920	0	58	40	44	946,930
1955–70	17,944	0	49	37	39	658,924
1971–89	17,123	0	33	23	23	391,187
Total	58,987	0	58	34	34	1,997,041

A total of 35,294 cohort members were alive at 31.12.2003. Among them the mean age at this time was 57 years. The oldest man was 99 years and the youngest 31 years. Members of sub-cohort C were on average very young (44 years) compared to those from sub-cohort A (74 years) and sub-cohort B (63 years) (see Table 6.1-6).

Table 6.1-6: Distribution of age as of 31 Dec 2003 for living subjects in years

Sub-cohort	no.	Min	Max	Mean	Median	Std
1945–54	7,497	63	96	74	74	5
1955–70	12,036	48	99	63	63	7
1971–89	15,761	31	84	44	44	7
Total	35,294	31	99	57	57	14

6.2 Description of deceased cohort members

A total of 20,920 cohort members were deceased by 31 December 2003 (see Table 6.2-1). Among them 14,796 from sub-cohort A, 5,181 from sub-cohort B and 943 from sub-cohort C. Mean age at death was 67 years in sub-cohort A, 60 years in sub-cohort B and 41 years in sub-cohort C. The youngest age at death was 17 years, the oldest 103.

Table 6.2-1: Distribution of age at death for deceased subjects by sub-cohort

Age at death	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
15 – 19	1	0.0	11	0.2	31	3.3	43	0.2
20 – 24	32	0.2	68	1.3	82	8.7	182	0.9
25 – 29	42	0.3	103	2.0	85	9.0	230	1.1
30 – 34	90	0.6	114	2.2	113	12.0	317	1.5
35 – 39	120	0.8	167	3.2	128	13.6	415	2.0
40 – 44	316	2.1	257	5.0	162	17.2	735	3.5
45 – 49	556	3.8	398	7.7	142	15.1	1,096	5.2
50 – 54	933	6.3	587	11.3	85	9.0	1,605	7.7
55 – 59	1,470	9.9	772	14.9	47	5.0	2,289	10.9
60 – 64	2,205	14.9	834	16.1	36	3.8	3,075	14.7
65 – 69	2,748	18.6	718	13.9	13	1.4	3,479	16.6
70 – 74	2,626	17.7	477	9.2	9	1.0	3,112	14.9
75 – 79	1,877	12.7	341	6.6	4	0.4	2,222	10.6
80 – 84	1,129	7.6	218	4.2	3	0.3	1,350	6.5
85 – 89	544	3.7	89	1.7	1	0.1	634	3.0
90+	107	0.7	27	0.5	2	0.2	136	0.7
Total	14,796	100.0	5,181	100.0	943	100.0	20,920	100.0

The cause of death was available for 93.6% of all deceased cohort members. This proportion differed slightly between the three sub-cohorts (see table 6.2-2). For 19,588 cohort members the cause of death was available.

Table 6.2-2: Availability of cause of death (COD) by sub-cohort

Sub-cohort	COD not available		COD available		Total	
	no.	%	no.	%	no.	%
1946–54	1,000	6.8	13,796	93.2	14,796	100.0
1955–70	293	5.7	4,888	94.3	5,181	100.0
1971–89	39	4.1	904	95.9	943	100.0
Total	1,332	6.4	19,588	93.6	20,920	100.0

Table 6.2-3 shows the source of information on cause of death (copies of death certificates from local health authorities or autopsy files from the Wismut Pathology Archives) and type of diagnose (autopsy or clinical diagnosis). For 18,201 cohort members death certificates were available from the local health authorities. Among them, for 13% (2,373) information was based on autopsies. For a total of 3,772 (19.3%) deceased cohort members autopsy files had been available at the pathology archive, which covers the years up to 1990.

Table 6.2-3: Source of information on cause of death (follow-up by local health authorities or pathology archive) by type of diagnose (autopsy or clinical diagnose)

Local health authorities	Pathology archive				Total	
	COD unknown		COD based on autopsy			
	no.	%	no.	%	no.	%
COD based on autopsy	1,832	9.4	541	2.8	2,373	12.1
COD based on clinical diagnose only	13,984	71.4	1,844	9.4	15,828	80.8
COD unknown	-		1,387	7.1	1,387	7.1
Total	15,816	80.7	3,772	19.3	19,588	100.0

With increasing year of death, the proportion of causes of death that were based on autopsy decreased (Table 6.2-4). For men who died after 1995 information on cause of death was based on autopsy for about 5 % only, while for those who died before 1970 these proportions were above 70%. However, it has to be kept in mind that for those who died in the earlier years a higher proportion of information on cause of death was based on the Pathology Archives. Moreover, in the former GDR a high autopsy rate was standard in contrast to West Germany. With the reunification of Germany in 1990 the autopsy rates in Eastern Germany dropped down.

Table 6.2-4: Distribution of year of death by type of diagnose (autopsy or not)

Year of death	No autopsy		Autopsy		Total	
	no.	%	no.	%	no.	%
< 1959	39	44.8	48	55.2	87	0.4
1960–1964	51	20.8	194	79.2	245	1.3
1965–1969	170	29.1	415	70.9	585	3.0
1970–1974	489	39.4	753	60.6	1,242	6.3
1975–1979	841	45.4	1,012	54.6	1,853	9.5
1980–1984	1,277	52.5	1,157	47.5	2,434	12.4
1985–1989	1,667	56.8	1,267	43.2	2,934	15.0
1990–1994	2,979	86.5	464	13.5	3,443	17.6
1994–1999	3,692	96.0	152	4.0	3,844	19.6
2000–2003	2,779	95.1	142	4.9	2,921	14.9
Total	13,984	71.4	5,604	28.6	19,588	100.0

Table 6.2-5 shows the distribution of cause of death by the 1-digit main group of ICD-10 and by sub-cohort. Overall, the most frequent group of cause of death were cardiovascular diseases (37.8%), followed by malignant tumours (32.5 %), respiratory diseases (10.2%) and accidents, suicide, etc. (8.1%). Due to the young age of sub-cohort C, the most frequent cause of death in this group was accidents (41%).

Table 6.2-5: Distribution of cause of death (main group of ICD 10) by sub-group

Main group of ICD 10	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
AB Infections	91	0.7	40	0.8	5	0.6	136	0.7
C Malignancies	4,628	33.5	1,581	32.3	164	18.1	6,373	32.5
D Benign Tumors	61	0.4	37	0.8	6	0.7	104	0.5
E Metabolic disord.	180	1.3	90	1.8	6	0.7	276	1.4
F Mental disorders	64	0.5	70	1.4	31	3.4	165	0.8
G Nervous system	85	0.6	40	0.8	8	0.9	133	0.7
H Eye diseases	1	0.0	-	-	-	-	1	0.0
I Cardiosvasc. Dis.	5,541	40.2	1,702	34.8	152	16.8	7,395	37.8
J Respiratory Dis.	1,693	12.3	281	5.7	24	2.7	1,998	10.2
K Digestive System	606	4.4	367	7.5	103	11.4	1,076	5.5
L Dis. of the skin	2	0.0	-	-	-	-	2	0.0
M Musculoskel. Dis	30	0.2	8	0.2	1	0.1	39	0.2
N Renal system	138	1.0	29	0.6	4	0.4	171	0.9
Q Malformations	2	0.0	-	-	-	-	2	0.0
R Others/Unknown	53	0.4	47	1.0	28	3.1	128	0.7
ST Accidents/Injuries	621	4.5	596	12.2	372	41.2	1,589	8.1
Total	13,796	100.0	4,888	100.0	904	100.0	19,588	100.0

A total of 6,373 cases of malignant tumours occurred in the cohort. Nearly fifty percent of them are lung cancer cases. The second most frequent cancer type was stomach cancer, followed by colon, prostate, pancreas, rectum and liver (see table 6.2-6). About 2% of all cancer cases had no specification on type of cancer (C80, C76, C78). For about 0.7 % of all cancers several sites were affected (C97).

Mean age at death from cancer was 63 years. The youngest one died aged 19, the oldest aged 90. 4,628 cancer cases occurred within sub-cohort A (mean age at death 66 years), 1,581 in sub-cohort B (mean age at death 61 years) and 164 cases in sub-cohort C (mean age at death 47 years). Overall 35.8 % (n=2,282) of the cancer deaths were autopsied.

A total of 3,016 lung cancer deaths occurred in the second mortality follow-up. 2,367 lung cancer deaths occurred in sub-cohort A (mean age at death 64 years), 603 in sub-cohort B (mean age at death 62 years) and 46 cases in sub-cohort C (mean age at death 52 years). The youngest lung cancer death was at age 30. 50% of the 3,016 lung cancer deaths were based on autopsy. This proportion was highest amongst sub-cohort A with 55% compared to sub-cohort B (35%) and to sub-cohort C (13%).

Table 6.2-6: Distribution of causes of death for cancer by 3 digit ICD10-code

3-digit ICD 10 code		no.	%
C00	Lip	3	0.0
C01/02	Tongue	20	0.3
C03	Gingiva	1	0.3
C04	Floor of mouth	12	0.2
C05	Palate	3	0.0
C06	Mouth others	2	0.0
C07	Parotis	5	0.1
C09	Tonsil	14	0.2
C10	Oropharynx	15	0.2
C11	Nasopharynx	4	0.1
C13	Hypopharynx	12	0.2
C14	Lip, mouth, oth.	8	0.1
C15	Oesophagus	126	2.0
C16	Stomach	595	9.3
C17	Small intestine	10	0.2
C18	Large intestine	291	4.6
C19	Rectosigmoid	16	0.3
C20	Rectum	222	3.5
C21	Anus	3	0.0
C22	Liver/bile duct	159	2.5
C23	Gallbladder	46	0.7
C24	Biliary tract	35	0.5
C25	Pancreas	229	3.6
C26	Digestive Sys.	14	0.2
C30	Nose, Ear	2	0.0
C31	Paranasal sin.	7	0.1
C32	Larynx	75	1.2
C33	Trachea	2	0.0
C34	Lung	3016	47.3
C37	Thymus	2	0.0
C38	Mediastinum	28	0.4
C39	Resp. tract, oth.	2	0.0
C40/41	Bone	13	0.2
C43	Melanoma	34	0.5
C44	Skin others	9	0.1

3-digit ICD 10 code		no.	%
C45	Mesothelioma	21	0.2
C47	Nervous sys.	4	0.1
C48	Peritoneum	10	0.2
C49	Connective tis.	12	0.1
C50	Breast	4	0.1
C60	Penis	3	0.1
C61	Prostate	264	3.4
C62	Testis	27	0.5
C64	Kidney	152	2.2
C65	Renal pelvis	14	0.2
C66	Ureters	5	0.1
C67	Bladder	174	2.6
C68	Urinary tract	3	0.0
C69	Eye	1	0.0
C70	Meninges	2	0.0
C71	Brain	109	1.7
C72	CNS	4	0.1
C73	Thyriod gland	19	0.3
C74	Adrenal gland	3	0.1
C75	Endocr. gland	2	0.0
C76	Unknown loc.	14	0.3
C77	Lymphnodes	1	0.0
C78	Respir./digestion	4	0.1
C78	Unknown loc.	4	0.1
C80	Not reported	115	1.7
C81	Hodgkin's Dis	31	0.6
C82/83	Non-Hodgkin	32	0.6
C84	T-Cell-Lymphom	4	0.0
C85	NHL, others	48	0.7
C88	Immunoprofil.	3	0.0
C90	Plasmocytom	55	0.7
C91	Lymph. leukemia	51	0.8
C92	Myeloi. leukemia	63	1.0
C94/95	Leuk. others	16	0.2
C96	Blood forming tis.	1	0.0
C97	Multiple loc.	63	1.0

6.3 Exposure to radiation

A total of 50,773 cohort members had ever been exposed to radon (86%), while 8,214 persons had never been exposed (14%). The proportion of never-exposed persons differs between the sub-cohorts (9.7% in A, 20.4 % in B and 13.0% in C). Table 6.3-1 shows the distribution of cumulative radon exposure in categories of WLM by sub-cohort. Cumulative exposures above 100 WLM were predominant in sub-cohort A (66%), compared to 21% in B and 0% in C, respectively. Overall a large number of cohort members have low cumulative exposures in the range 1 to 10 WLM (28%), these members are mainly from sub-cohort C.

Table 6.3-1: Cumulative exposure to radon in WLM by sub-cohort

Cumulative radon exposure in WLM	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
0	2,328	9.7	3,660	20.4	2,226	13.0	8,214	13.9
> 0 – 5	1,970	8.3	2,763	15.4	7,132	41.6	11,865	20.1
> 5 – 10	672	2.8	1,208	6.7	2,812	16.4	4,692	8.0
> 10 – 50	2,126	8.9	4,185	23.3	4,871	28.4	11,182	19.0
> 50 – 100	983	4.1	2,251	12.5	82	0.5	3,316	5.6
> 100 – 500	5,788	24.2	3,194	17.8	-	-	8,982	15.2
> 500 – 1000	5,446	22.8	592	3.3	-	-	6,038	10.2
> 1000	4,607	19.3	91	0.5	-	-	4,698	8.0
Total	23,920	100.0	17,944	100.0	17,123	100.0	58,987	100.0

The mean cumulative radon exposure among exposed cohort members is 280 WLM, ranging from 583 WLM in sub-cohort A, to 105 WLM in sub-cohort B and 9 WLM in sub-cohort C (Table 6.3-2). The maximum exposure was 3,224 WLM. The mean age at first exposure was higher in sub-cohort A with 28 years compared with 21 years in sub-cohort C. Overall the mean duration of exposure was 11 years.

Table 6.3-2: Exposure characteristics among radon exposed miners by sub-cohort

Sub-cohort	no	Mean age at first exposure in years (Range)	Mean duration of exposure in years (Range)	Mean WLM (Range)
1946 – 54	21,592	28 (14 – 67)	14 (1 – 44)	583 (>0 – 3,224)
1955 – 70	14,284	24 (14 – 66)	12 (1 – 35)	105 (>0 – 1,253)
1971 – 89	14,897	21 (15 – 61)	7 (1 – 19)	9 (>0 – 65)
Total	50,773	25 (14 – 67)	11 (1 – 44)	280 (>0 – 3,224)

Figure 6.3-1 shows the annual exposure to radon in WLM among exposed cohort members given in quartiles (25,50,75). The highest radon levels occurred in the years 1954 to 1956. The maximum cumulative radon exposure per year was 375 WLM in 1956. The mean annual radon levels in the cohort strongly decreased after 1964 to a mean level of below 2 WLM per year after 1972.

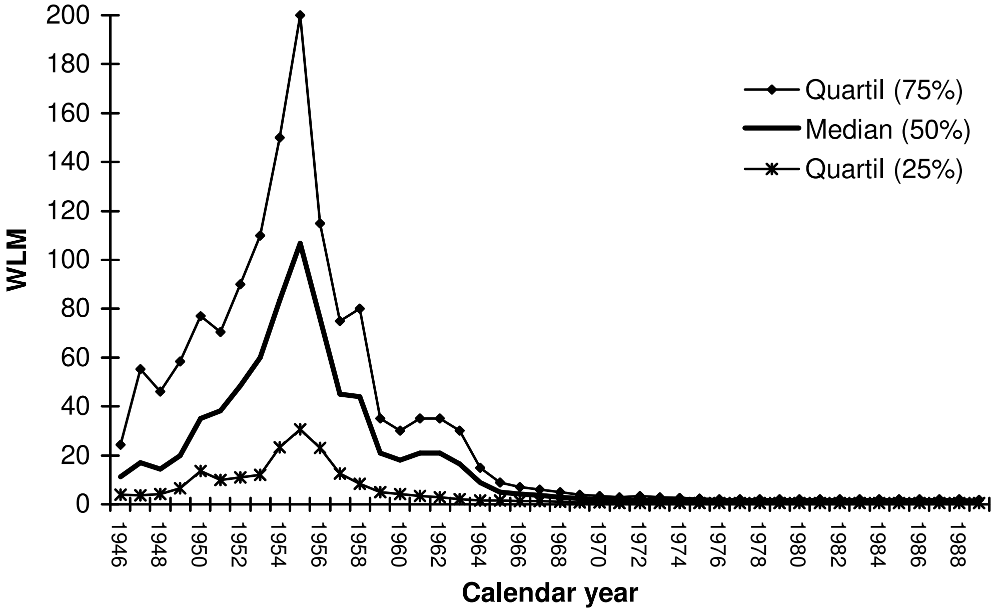

Figure 6.3-1: Quartiles (25%, 50%, 75%) of annual exposure to radon in WLM among exposed cohort members (n=50,773)

When exposure to long-lived radionuclides (LRN) is considered, a total of 14% of the cohort members had never been exposed to LRN (see Table 6.3-3). Overall, the mean cumulative LRN exposure was 4 kBqh/m^3 with a maximum of 132 kBqh/m^3. Mean exposures had been substantially higher in sub-cohort A, compared to sub-cohort B or C.

Table 6.3-3: Cumulative exposure to long-lived radionuclides (LRN) by sub-cohort

Cumulative exposure to LRN in kBqh/m^3	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
0	2,333	9.8	3,667	20.4	2,226	13.0	8,226	13.9
> 0 – 0.5	2,830	11.8	4,100	22.8	12,673	74.0	19,603	33.2
> 0.5 – 1	1,785	7.5	2,127	11.9	1,490	8.7	5,402	9.2
> 1 – 5	7,970	33.3	5,821	32.4	729	4.3	14,520	24.6
> 5 – 10	3,660	15.3	1,275	7.1	5	0.0	4,940	8.4
> 10 – 50	5,212	21.8	943	5.3	-	-	6,155	10.4
> 50	130	0.5	11	0.1	-	-	141	0.2
Total	23,920	100.0	17,944	100.0	17,123	100.0	58,987	100.0

Figure 6.3-2 gives the individual exposure to long-lived radionuclides in kBqh/m^3 per year for exposed cohort members. The highest LRN levels occurred in the years 1958 to 1965. The maximum cumulative LRN exposure per year was 28.8 kBqh/m^3.

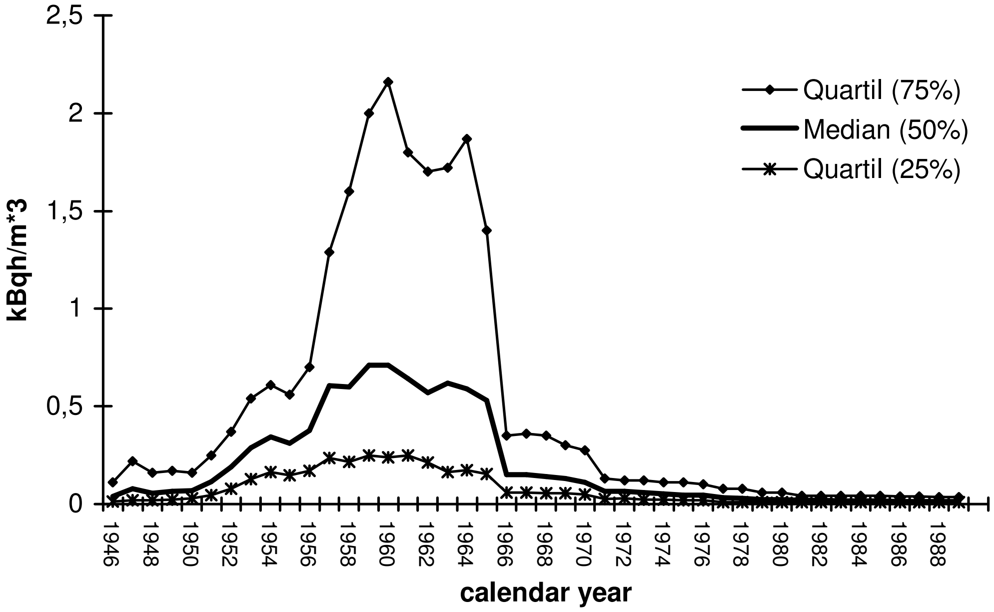

Figure 6.3-2: Quartiles (25%, 50%, 75%) of annual exposure to long-lived radionuclides in kBqh/m^3 among exposed cohort members (n=50,761).

Table 6.3-4 shows the distribution of exposure to external gamma radiation. Overall, the mean cumulative gamma exposure was 47 mSv with a maximum of 909 mSv. Mean exposures had been substantially higher in sub-cohort A, compared with sub-cohort B or C.

Table 6.3-4: Cumulative external gamma radiation in mSv by sub-cohort

Cum. exposure to gamma radiation in mSv	Sub-cohort by begin of employment						Total	
	1946–1954		1955–1970		1971–1989			
	no.	%	no.	%	no.	%	no.	%
0	2,333	9.8	3,667	20.4	2,226	13.0	8,226	13.9
> 0 – 1	1,330	5.5	974	5.4	1,482	8.6	3,786	6.4
> 1 – 5	2,872	12.0	2,738	15.3	4,017	23.5	9,627	16.3
> 5 – 10	2,311	9.7	1,800	10.0	2,767	16.2	6,878	11.7
> 10 – 50	7,850	32.8	5,023	28.0	4,986	29.1	17,859	30.3
> 50 – 100	2,938	12.3	1,686	9.4	1,205	7.0	5,829	9.9
> 100 – 500	4,173	17.4	2,042	11.4	440	2.6	6,655	11.3
> 500 – 909	113	0.5	14	0.1	-	-	127	0.2
Total	23,920	100.0	17,944	100.0	17,123	100.0	58,987	100.0

Figure 6.3-3 gives the annual whole-body exposure to external gamma radiation in mSv per year for exposed cohort members. The highest gamma radiation levels occurred in the years 1963 to 1965. The maximum cumulative gamma exposure per year was 127 mSv.

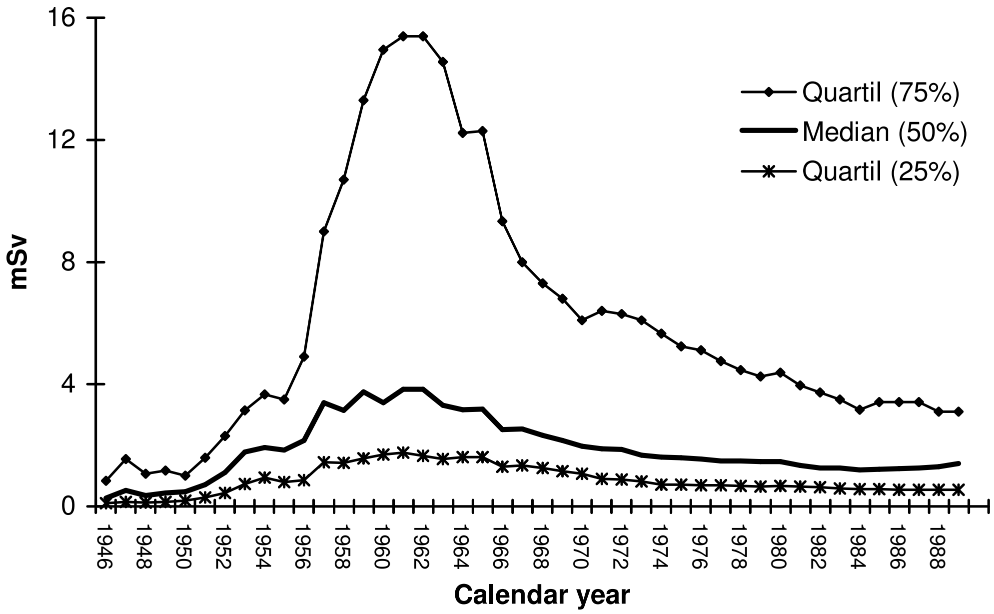

Figure 6.3-3: Quartiles (25%, 50%, 75%) of annual exposure to external gamma radiation in mSv among exposed cohort members (n=50,761).

Levels of exposure to radiation depend on place of work . Employees who only worked underground have an appreciably higher exposure to radon and its progeny compared to workers in processing and milling or open pit miners or workers at the surface (Table 6.3-5). In contrast, exposure to LRN and gamma do not show such a great dependence on place of work.

Table 6.3-5: Mean cumulative exposures by workplace among exposed cohort members

Work Place	Radon and its progeny in WLM	LRN in kBqh/m^3	Gamma in mSv
Underground only (n = 39,726)	332	4.2	51.2
Processing/Milling only (n = 4,451)	8	4.1	28.8
Open pit mining only (n = 1,277)	3	2.8	10.2
Surface only (n = 1,093)	2	0.5	3.2

6.4 Exposure to dust and arsenic

A brief description of the exposure to fine dust, silica dust and arsenic is given in Table 6.4-1. Due to imprecise working histories exposure estimations for fine dust and silica dust could not be carried out for 292 persons, and for 43 persons (exposures to arsenic), respectively. In contrast to radiation exposure, practically all cohort members are exposed at some time to fine dust or silica dust. Because arsenic exposure was only present in some mining objects in Saxony, only about one third of the cohort has been exposed to arsenic at some time.

Table 6.4-1: Cumulative exposures to fine dust, silica dust and arsenic in the cohort

	Fine dust in dust-years [1]	Silica dust in dust-years [1]	Arsenic in dust-years [1]
No. of exposed cohort members	58,695	58,658	18,234
No. of not exposed cohort members	0	37	40,710
Missing information on exposure	292	292	43
Mean (exposed only)	36.6	5.9	121.2
Maximum (exposed only)	315.2	56.0	1,417.4

[1] *One dust-year is defined as exposure to 1 μg/m³ for arsenic over 220 shifts each at 8 hours and as exposure to 1 mg/m³ for fine dust or silica dust over 220 shifts each at 8 hours*

Figure 6.4-1 gives the annual exposure to cumulative fine dust in dust-years for exposed cohort members. The highest exposure levels occurred in the years 1948 to 1956.

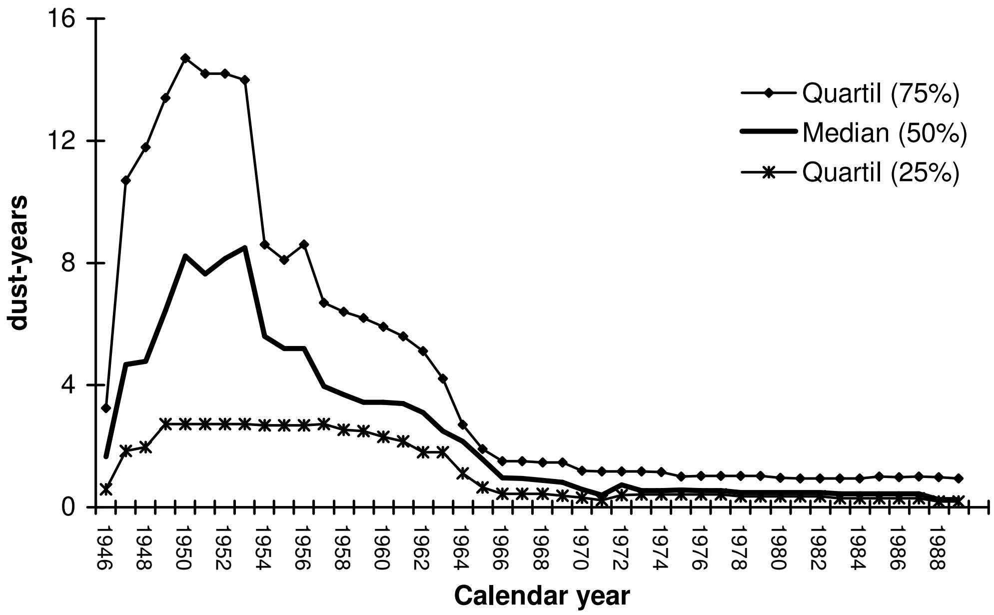

Figure 6.4-1: Quartiles (25%, 50%, 75%) of annual exposure to fine dust in dust-years among exposed cohort members (n=58,695).

Figure 6.4-2 gives the annual exposure to cumulative silica dust in dust-years for exposed cohort members. The highest exposure levels occurred in the years 1948 to 1956. The pattern of exposure is the very similar to that of fine dust exposure. With respect to arsenic exposure the highest exposures occurred between 1947 and 1952 (Figure 6.4-3).

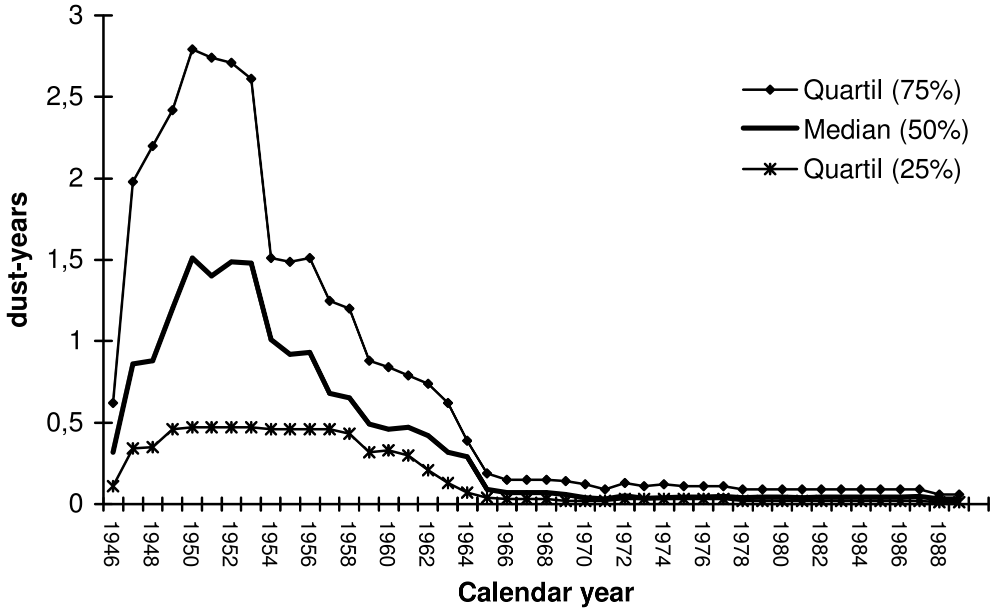

Figure 6.4-2: Quartiles (25%, 50%, 75%) of annual exposure to silica dust in dust-years among exposed cohort members (n=58,658).

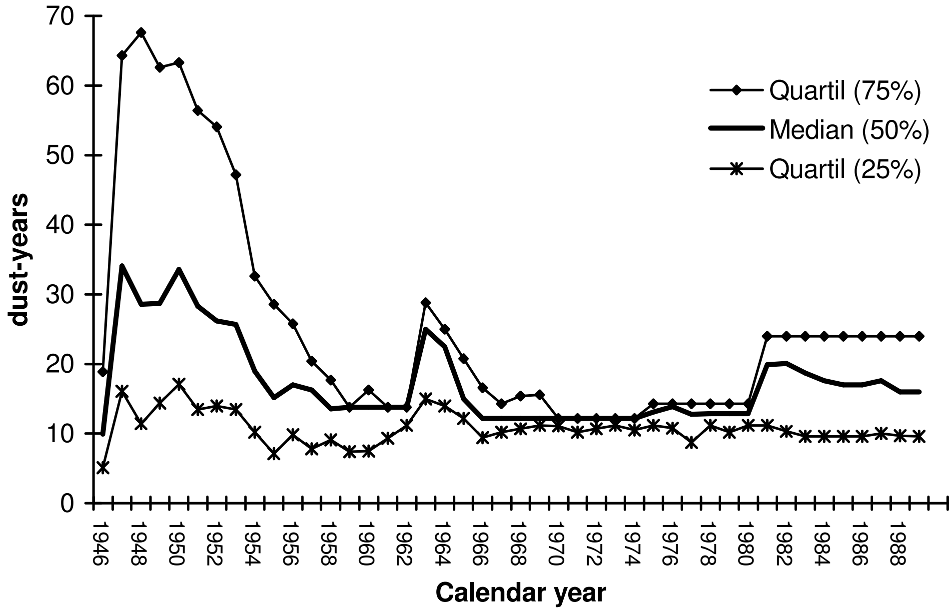

Figure 6.4-3: Quartiles (25%, 50%, 75%) of annual exposure to arsenic in dust-years among exposed cohort members (n=18,234).

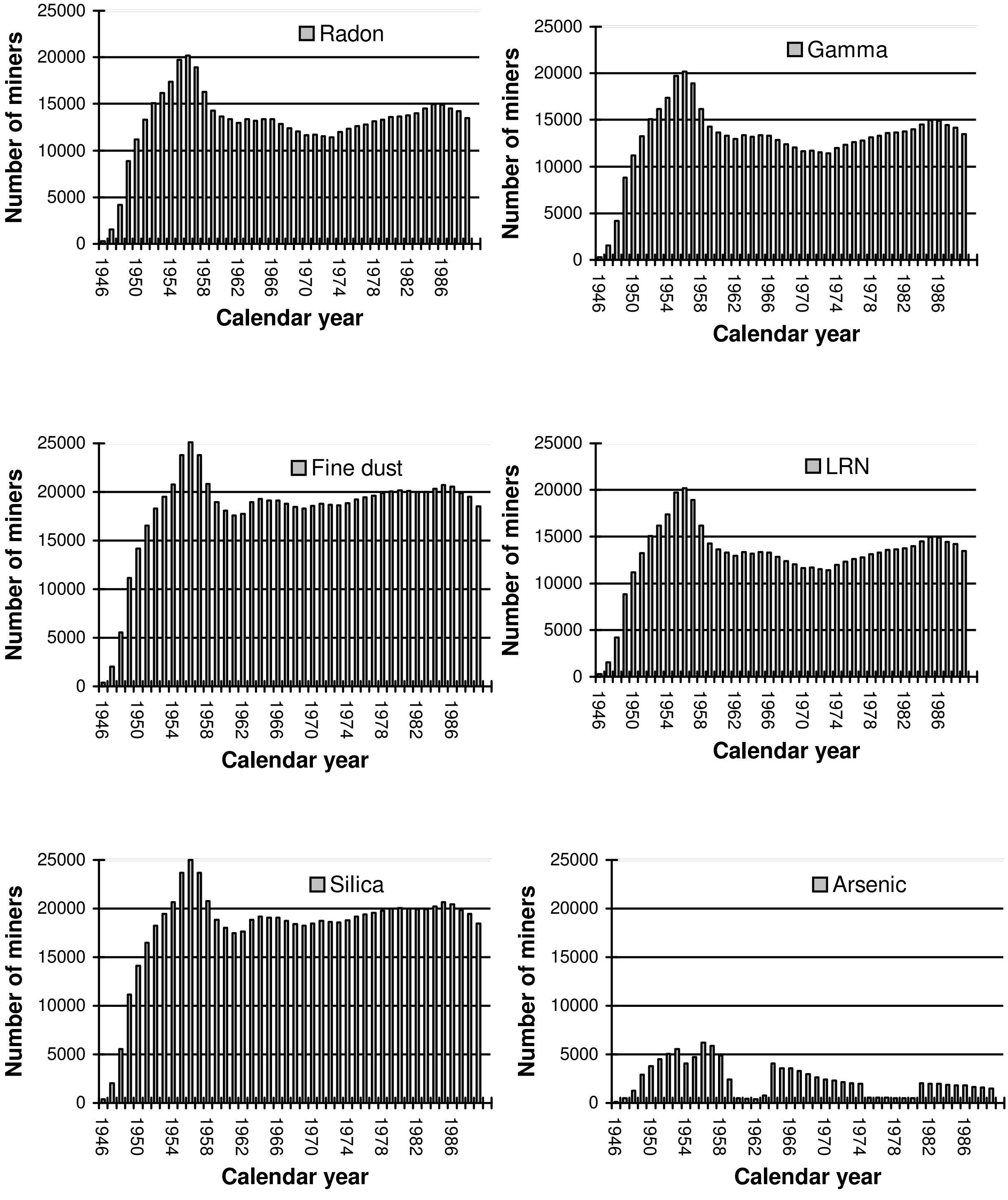

Figure 6.4-4 : Number of exposed cohort members per calendar year with respect to exposure to radon, LRN, gamma radiation, fine dust, silica and arsenic

Figure 6.4-4 shows the number of exposed cohort members by type of exposure. Nearly all cohort members are exposed to fine dust or silica, whereas only a small proportion is exposed to arsenic.

7 RELATED STUDIES

7.1 Nested case-control study on lung cancer

A nested case-control study on lung cancer including 704 Wismut cohort members who died of lung cancer (cases) and 1,398 Wismut cohort members without lung cancer (controls) matched individually for birth year and attained age has been conducted. Additional information on smoking, occupations outside the Wismut company, and medical examinations was collected from the miners themselves, their next-of-kin or the health archives of the Wismut company. For 421 cases and 620 controls smoking information could be collected. The risk for lung cancer due to radon was only marginally modified when additional adjustment for smoking was performed, indicating smoking to be an unlikely confounder in the cancer risk attributable to radon exposure.

7.2 Molecular epidemiological studies

No biological material is collected from the cohort members themselves, because the follow-up is passive without personal contact to the cohort members. However, other procedures are currently tested in order to establish a biobank of high and low radon exposed former Wismut employees including the same exposure information like in the cohort. Several thousands of former Wismut employees are regularly undergoing medical examinations that are offered by the Wismut company. During these visits blood will be collected for a sub-sample of former Wismut miners. Next to that, it is planned to isolate DNA from autopsy material of former Wismut employees who died from lung cancer.

Presently three molecular epidemiological studies on former Wismut employees are already ongoing. One study investigates molecular signatures of the combined effects of radon and arsenic in lung cancer by examining the characteristic protein expression in the different cell types of lung cancer. In another study blood samples from former Wismut employees were analysed regarding potential biomarkers for arsenic- and/or ionising radiation exposure with proteomics and RNA microarray technologies. A third study investigates individual radiosensitivity based on blood samples of the offspring and relatives of Wismut employees who died of lung cancer prior to the age of 51 years.

7.3 European Alpha-Risk Project

Within the EU-alpha-risk project the French, Czech and German cohort studies on former uranium miners are investigated with respect to the cancer risk effects due to low radiation exposure. Moreover, organ doses for several organs and the corresponding risks are calculated. The Wismut cohort data based on the first mortality follow-up by 1998 restricted to sub-cohort B and C (begin of employment after 1954) are included in the EU-alpha risk project.

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