DRAFT

DOCKET NO. 40-8778

LICENSE NO. SMB-1393

LICENSEE: MOLYCORP, INCORPORATED, WASHINGTON, PA.

SUBJECT: DRAFT SAFETY EVALUATION REPORT, LICENSE AMENDMENT REQUEST DATED FEBRUARY 8, 1996, CONCERNING THE CONSTRUCTION AND OPERATION OF AN INTERIM STORAGE STRUCTURE

1.0 Introduction

Molycorp, Incorporated (hereafter referred to as the licensee), by letter to the U.S. Nuclear Regulatory Commission (NRC) dated February 8, 1996 (ref. a), requested approval to construct a temporary storage facility on its Washington, Pennsylvania site, for the purpose of temporarily storing soil from its York, Pennsylvania, facility. Both the Washington and York facilities have been in the business of manufacturing rare earth elements for use in the production of metal alloys. The Molycorp Washington Source Materials License, No. SMB-1393, was last renewed on October 27, 1992, and is currently under timely renewal during NRC review of the license application (ref. b), dated June 30, 1997. The York Source Materials License, No. SMB-1408, was issued on August 24, 1994. In a parallel action, NRC is also reviewing the site decommissioning plans (SDPs) for both the Washington (ref. c) and York (ref. d) facilities.

1.1 Purpose and Need for the Proposed Action

The purpose of this action is to review for approval the proposed construction and operation of an interim storage facility at the licensee's Washington, Pennsylvania, site. This action could facilitate cleanup of contaminated soils from the licensee's York, Pennsylvania, site and release of the York site for unrestricted use. The licensee, in a parallel action, has also proposed to build a permanent disposal cell on the Washington site to dispose of approximately 100,000 cubic yards of contaminated soils from the Washington site. If this parallel action is approved (the licensee would construct and operate the interim storage facility at its own financial risk), decommissioning waste from both facilities would be disposed in the permanent disposal cell at the Washington site. This would ultimately allow termination of both the York (SMB-1408) and Washington (SMB-1393) licenses.

1.2 Description of Proposed Action

The objective of the proposed action is to construct and operate an interim storage facility at the Washington, Pennsylvania, Molycorp site. This action would involve transport of contaminated soils to the Washington, Pennsylvania, facility , and then temporarily storing these soils in the temporary structure until NRC makes a decision regarding the acceptability of a permanent disposal cell on the Washington site. The temporary storage structure would be located near the

southwest boundary of the Washington site and has been designed to: (1) provide structural stability for the waste soils under anticipated loads; (2) protect the contaminated soils from wind and water erosion; and (3) prevent commingling of contaminated York soils with those present on the Washington site.

2.0 Description/Operating History of Washington and York Facilities

2.1 Description of Washington Site

The licensee owns two rare earth processing facilities in the Commonwealth of Pennsylvania. The larger of these sites is located in Washington, Pennsylvania, on a 59 acre site. The other processing facility is located in York, Pennsylvania, on a small tract of land of approximately 5 to 6 acres. Both facilities have manufactured rare earth elements for use in the production of metal alloys. Molycorp has notified NRC of its intent to cease operations at both facilities, as indicated in its SDPs submitted in accordance with 10 CFR 40.36, "Timeliness in Decommissioning Material and Fuel Cycle Facilities (Ref. e).

The Molycorp, Washington, site is located in Washington, Pennsylvania, in Washington County, 35 miles from the city of Pittsburgh in southwestern Pennsylvania and is the proposed location of the storage facility intended for York's thoriated-soil type waste. The fenced area of the Washington site contains what was once the rare earth processing facility and occupies 20 acres of the 59 acre site. This facility began operation in the 1920s and, due to a fall off in demand for its alloy products, has experienced decreased throughput.

2.2 Facility Operating History

2.2.1 Washington Facility

The licensee has produced rare earth metals for the manufacture of alloys with varying properties since the 1920s. Principal metals in the ores processed to make these alloys have included iron, molybdenum, and tungsten. Current site activities include the purchasing and reselling of alloys. However, the plant has not processed ferro-columbium (iron-niobium) ores since 1971. The ferro-columbium ores processed prior to 1971 contained naturally occurring, radioactive thorium that was a constituent in the slag produced in the high temperature roasting furnaces. Prior to receiving a license, the licensee deposited this waste slag on the site as fill and then covered it with three to four feet of top soil. The site is also the location of a slag pile containing approximately a half million cubic feet of thoriated slag. This pile has been stabilized and is now covered with vegetation. The licensee proposes to move the slag fill and the contaminated pile to a permanent disposal unit to be constructed on site. Evaluation of the safety of this permanent disposal facility is not included in this SER.

2.2.2 York facility

The Molycorp, York, facility produced metal alloys in a process that extracted thorium and small concentrations of uranium from bastnasite ores in liquid recovery process. A cerium concentrate solution was used in this process to dissolve the thorium and uranium containing ores. This process resulted in contamination of soils and structures at the facility. The licensee has proposed in its SDP to excavate approximately 5,000 cubic yards of waste soils for transport to the Washington facility for interim (5 to 10 years) storage.

3.0 Radiological Status of Thorium Contaminated Soils

3.1 Radiological Status of Soils to be Transported from York

The applicant has reported that soils at the York facility average approximately 100 pCi/gram for thorium with its daughters down to approximately 3.5 feet below grade and that exposure rates resulting from this residual activity are less than 57 micro-rem/hour above background (when measured at a distance of 1 meter from the surface of the soil and when averaged over areas not exceeding 100 square meters). NRC interim radiological cleanup criteria for cleaning up contaminated soils for unrestricted release are found in the 1981 Branch Technical Position (BTP) (Ref. f) dated October 23, 1981, "Disposal or Onsite Storage of Thorium and Uranium Wastes from Past Operations." The above stated average concentration of approximately 100 pCi/gram of unexcavated soils at York will need to be reduced to the BTP Option 1 limit which is 10 pCi/gram before the site could be released for unrestricted use. It is estimated that this will result in the generation of approximately 5,000 cubic yards of waste soils at an average concentration of 100 pCi/gram.

3.2 Radiological Status of Soils Already on the Washington Site

Final characterization of the Washington soils is not complete but preliminary indications are that concentrations of thorium contaminated soils at the Washington site probably exceed those at the York site. The licensee's current estimate of the average concentration of thorium for Washington soils is approximately 80 pCi/gram for mixed slag/surface soils (with a 10,000 cubic yard volume to be excavated at this concentration). Concentrations in the southwest slag pile at the Washington site are reported up to 1700 pCi/gram for Th-232. The anticipated volumes of soil excavated for disposal in Washington may ultimately exceed by several orders of magnitude the excavated soil disposal volumes at York. Because of the difference in the source terms for these facilities and in the event that approval is not granted for final disposal of the York soils in a Washington disposal unit, measures are being taken to prevent the commingling of York and Washington soils and NRC has required that the licensee make provisions for containment during any interim storage period. Therefore, this action does not involve Washington soils.

3.3 Radiological Status of Surface and Ground Waters at Washington Site

Sampling and analysis in the past two years has detected no thorium in surface or ground water at either the Washington or York site.

4.0 Evaluations

4.1 Task Management, Project Organization and Training

The process of excavating, loading, and transporting contaminated soils from the York facility to the Washington facility is included as part of the decommissioning activities described in the "Decommissioning Plan for the York, PA Facility" (Ref. c) and in the "Site Decommissioning Plan for Molycorp's Washington, PA Facility" (Ref. d). These documents also contain a description of the decommissioning organization (see attached Washington Site Decommissioning Project Safety Organization Chart) and its responsibilities during the project with a schedule for accomplishing the activities. Tasks associated with constructing and operating the interim storage facility are described in documents supporting the amendment request (Refs. g thru i).

The Molycorp project manager will function as the Molycorp representative for the decommissioning project and will provide oversight for all project activities. The Molycorp project manager will also coordinate cost and schedule reporting with the contractor. The Site Health and Safety/Radiation Safety Officer (RSO), who, during daily activities reports to the Site Manager (responsible for the day to day activities on the project) , will receive directions from the Corporate Health Physicist. The NRC staff has examined the RSO position with regard to the organizational structure presented for the proposed project and has concluded that the RSO will have the authority necessary to perform his functions (i.e., to prevent the performance of work activities that might jeopardize the safety of personnel, violate approved plans, procedures, or practices, that could result in the unwarranted release of contamination).

This project will employ a radiological engineer (RE) who will participate in project planning and reporting activities to ensure that regulatory compliance is achieved. The RE will also be responsible for the adequacy of plans and procedures and develop project specific plans and work instructions (radiation work permits) to assure that radiological safety is maintained in the execution of decommissioning activities. An important function of the RE will be to ensure that radiation exposures to personnel and the environment are maintained As Low As Reasonably Achievable (ALARA) and to ensure that radiation levels are always within regulatory limits.

The licensee has agreed to conduct a training program that meets the requirements of 10 CFR 19.12, "Instructions to Workers." All contractor and subcontractor personnel working on site will be trained in this regard before participating in decommissioning activities. The RSO will maintain training records for all personnel working on site. Qualifications for both the RSO and

the RE are discussed in References c and d. The staff has concluded that the proposed task management, project organization, and training for the proposed action are acceptable.

5.0 Radiation Protection Program

The licensee's radiation protection program for the Washington, Pennsylvania, Molycorp facility will be implemented to provide radiological protection for both the York and Washington sites during the period of construction and operation of the interim storage facility. The purpose of the plan is to establish and maintain policies and procedures conducive to the safe handling of radioactive materials and to delineate responsibilities for radiological safety in working with radioactive materials. This plan has also been developed to provide for the health and safety of members of the public while on the Molycorp site. The plan addresses personnel radiological safety responsibilities, posting and labeling of areas containing radioactivity, personnel protection, permissible exposure limits, contamination control, specific procedures for handling material, radiological surveys, and emergency procedures. NRC considers this program, developed for emergency and normal operating conditions, to be acceptable during construction and operation of the interim storage facility.

6.0 Record of Regulatory Compliance

The last inspection at Molycorp's Washington facility, on October 15 and 16 , 1997, did not find any items of noncompliance. In addition, the licensee has had no items of noncompliance identified during three inspections performed in the last five years. The NRC staff's examination of the licensee's compliance history reveals successful performance in working with radioactive materials and proper management of the storage operation can be anticipated.

7.0 Physical Security

Subpart I of 10 CFR Part 20 (section 20.1801), "Storage and Control of Licensed Material," requires that the licensee secure from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. The proposed storage area will be located in the controlled area inside the main fence that borders the site. This fence is locked to secure licensed material from access and during times, when the fence is opened, a guard is present to provide surveillance of the licensed material. The NRC staff considers this level of security adequate for the type of licensed material proposed for storage on site.

8.0 Stability of the Storage Structure

The temporary storage structure proposed by the applicant would be constructed on a slope and predominately below-grade. A concrete block wall would be constructed on the slope face to act as a gravity retaining structure. The remaining three sides of the temporary storage structure would be graded to a one horizontal to one vertical gradient (the remaining base of the excavation would be at elevation 1025 feet above sea level). Concrete fabric forms will be

placed on the three excavated side slopes. Prior to placement of the York waste soils, a high density polyethylene geomembrane liner would be placed on the bottom and all four sides of the structure. In addition, a geomembrane layer, of the same material, would be placed over the waste soils (clean will be placed and graded above the geomembrane layer would promote drainage away from the temporary storage structure). The following discussion is a review of the licensee's characterization of the temporary storage structure and an evaluation of its engineering design and construction details.

8.1 Geotechnical Characterization

The NRC staff reviewed the licensee's investigation of the temporary site in its effort to characterize the subsurface conditions. The characterization consisted of test boring exploration, laboratory testing, and analysis of the stratigraphy. The results of the site investigation and laboratory testing program were used to develop the stratigraphic conditions of the subsurface materials. The test borings indicated existing fill to depths of six to 25 feet. The licensee describes the fill as non-process slag, gravel, spent refractory, cinders and sand. The standard penetration resistance values (N-values) for the fill ranged from 3 to 32 blows per foot. Beneath the fill, a layer of clay, which included discontinuous sand layers, was encountered above the shale bedrock. The depth to bedrock ranged from 21 feet below existing grades on the west side to 32 feet on the ease side. N-values for the clay layer ranged from 2 to 39 blows per foot. Higher N-values were generally reported for the weathered rock zone and unconfined groundwater was encountered in the test borings near an elevation of 1020 feet above sea level. The NRC staff has concluded that the geotechnical investigations conducted at the site have adequately established the stratigraphy and that the applicant's subsurface explorations are adequate to support the assessment of the geotechnical stability of the temporary storage facility.

8.2 Engineering Design

The site characterization of the temporary storage site (presented in section 8.1 above) served as the basis for the licensee's proposed engineering design. The NRC staff reviewed important aspects of the geotechnical design including: slope stability; settlement analysis; retaining wall design; and geomembrane design.

8.2.1 slope stability

Factors that affect slope stability include: slope geometry; soil stratigraphy; soil parameters (including shear strength, unit weight, moisture content, and pore pressure distribution); and phreatic surface.

To evaluate the factor of safety against slope failure, the licensee used the computer code PCSTABL5 (Modified Bishop method). Utilizing a phreatic surface consistent with the observed groundwater level, the licensee modeled two sections. The cut slope section with a 45 degree slope gradient was modeled including the placement of the concrete-filled fabric form.

The final section with a 18 degree slope gradient was modeled including the retaining wall. The licensee's calculated factors of safety for the static conditions were 1.157 and 1.839, respectively. The pseudo-static (seismic) factors of safety for both sections were above unity. Due to the licensee's inclusion of a concrete-filled fabric form layer in the cut slope model and the existence of perched water within the existing embankment, NRC staff will require the licensee to report any slope instabilities which occur prior to or during construction placement of the concrete layer. The licensee will also be required to submit to NRC for approval the method it will employ to repair the cut slope.

NRC staff's independent analysis of the final section of the storage structure resulted in a factor of safety of 1.48. This factor of safety is considered acceptable.

8.2.2 settlement analysis

The licensee has calculated the settlement of the soft clay layer using Terzaghi's one-dimensional consolidation theory. The current and future stress states were estimated from the existing and proposed grades. The compression index of the clay was estimated using empirical correlations with the liquid limit. A total settlement of 11.2 inches was estimated. The licensee further estimates that differential settlement could be as high as 9.2 inches over 11 feet of the soft clay layer. This estimated differential settlement translates to a geomembrane strain of 3.2 percent and NRC staff considers this acceptable when evaluated against the manufacturer's specifications.

8.2.3 retaining wall design

The licensee provided design calculations for the retaining wall using a wall height of 6 feet and soil properties consistent with the slope stability analyses. NRC staff's review of this design indicates that the retaining wall appears to be appropriately designed to resist the anticipated loads.

8.2.4 geomembrane design

The licensee's geomembrane design includes an anchor trench along the top of the slope and a cushioning geotextile over the geomembrane layer on the bottom. The maximum estimated strain (discussed in section 8.2.2, above) is well within the design limit of 13 percent elongation at yield. The staff concludes that the design is acceptable.

8.3 Geotechnical Construction Details

8.3.1 construction methods and features

The NRC staff has reviewed and evaluated the geotechnical construction criteria. The excavation, placement, and compaction methods presented are generally planned in accordance

with standard practice and the liner systems will be installed in accordance the manufacturer's recommendations. The NRC staff concludes that the plans and drawings adequately convey the proposed design features.

8.3.2 testing and inspection

The NRC staff has reviewed and evaluated the manufacturer's testing and quality control inspection specifications. The licensee has committed to testing and inspection operations performed by a qualified geotechnical laboratory. NRC staff considers the testing and inspection program to be acceptable.

8.3.3 geomembrane

The specifications for the geomembrane layer were reviewed and found to be consistent with the analysis. Quality control and inspection procedures are deemed to be adequate.

9.0 Summary of Environmental Assessment

The environmental assessment prepared for this proposed action has: (1) evaluated the radiological status of the Molycorp Washington Pennsylvania site, as it relates to the temporary storage of York soil/slag waste; (2) assessed four reasonable alternatives to construction of the temporary storage facility on the Molycorp Washington site; and (3) evaluated the environmental impacts associated with the assessed alternatives. The conclusion of the environmental assessment (EA) is that the proposed action will have no significant impact on the surrounding environment.

10.0 Summary and Conclusion of Safety Evaluation

The safety evaluation for this proposed action has evaluated: (1) the task management organization for the interim storage project; (2) the licensee's radiation protection program; (3) the licensee's record of compliance with NRC regulations; (4) the structural stability of the interim storage facility; and (5) the physical security of the storage facility. Based on this evaluation, the staff has determined that the licensee has provided an adequate program and basis for the safe construction and operation of the interim storage facility and that the proposed action can be carried out in accordance with NRC's regulations. In addition, as documented in the EA, the proposed action will not result in a significant impact on the environment.

11.0 Recommendations

Based on the foregoing evaluation, the NRC staff recommends:

1. That the license for the Molycorp Washington, Pennsylvania facility (License No. SMB-1393) be amended to allow the construction and operation of an interim storage facility

for the purpose of storing soil waste generated in the decommissioning of the Molycorp facility (License No. SMB-1408) in York, Pennsylvania; and

2. That the Molycorp Washington license be amended to incorporate the conditions contained in Section 12.0 of this document, as it applies to the license.

12.0 License Conditions for the Molycorp Washington License

EA and SER, General License Condition No. 13

Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in items 6, 7, and 8, of this license in accordance with statements, representations, and procedures contained in Molycorp letters dated November 27, 1973 and January 30, 1974, the Molycorp application dated December 26, 1974, Molycorp letters dated July 13, 1992, and September 25, 1992. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters unless the statements are more restrictive than the regulations.

EA Section 1.2, License Condition No. 8A

A. 12 x 10 exp 4 Kgs

Page 6, EA Section 5.2, License Condition No. 14F

14. Schedule for Decommissioning Site:

F. Six months after the date of issuance of this amendment, Molycorp will update their decommissioning funding plan to more accurately list the cost associated with disposal of York soil/waste in the proposed Washington Molycorp permanent impoundment.

Page 6, EA Section 6.0 License Condition No. 15

15. Sampling of Airborne Particulate

The licensee will conduct the airborne particulate sampling discussed in section 6.0 of the EA dated 11/26/97 and described in the "Draft Response to U.S. NRC Request for Additional Information Temporary Thorium Storage Structure Final Design Report," dated December 20, 1996, during dumping, grading, and storage operations. This monitoring will employ equipment such as a PDM-3 Miniram Dust, Aerosol, Fume and Mist Monitor (or equivalent). In the event that worker exposure exceeds 10 percent of the concentration limits for soluble thorium 232, administrative controls or other engineering methods will be employed to reduce exposures or protective equipment such as respirators will be used to mitigate exposure of workers to dust..

DRAFT

Page 10, EA Section 7.2.2.2, License Condition No. 16

The Licensee will conduct annual monitoring of ground water in the vicinity (one up gradient well MW-31 and three down gradient wells MW-27, MW-28, and MW-30) of the interim storage structure in accordance with representations made in its amendment request dated February 8, 1998. The wells will be sampled for Th-232, Ra-226, total uranium, and for sulphate and chloride anions.

Page 11, EA Section 7.2.2.3, License Condition No. 17

The licensee will perform semi-annual sampling of surface water points currently sampled on an annual basis for the slag pile located in the southwestern area of the site.

Page 8, SER Section 7.3.2, License Condition No. 18

With regard to preparation and construction of the storage embankment and liner:
(1) The licensee shall report any slope instabilities of the engineered embankment that occur prior to or duing placement of the concrete fabri-form layer; (2) In the event that slope failure occurs, the licensee will submit to NRC for approval the method it will employ to repair the instability; and (3) Following installation of the liner, the licensee shall submit to NRC for approval the manufacturers liner installation certification prior to placement of the waste.

13.0 References

a. Molycorp, Incorporated, "Materials to Support a License Amendment Request for Interim Storage of Molycorp, York, PA Facility Material," letter from B. Dankmyer, Molycorp to L. Person, NRC, dated February 8, 1996.

b. Molycorp, Incorporated, "Molycorp Inc. Washington Pennsylvania NRC License SMB 1393 Renewal Application," dated June 30, 1997.

c. Molycorp, Incorporated, "Site Decommissioning Plan for Molycorp's Washington, PA Facility," dated July 19, 1995.

d. Molycorp, Incorporated, " Decommissioning Plan for the York, PA Facility," dated August, 1995.

e. U.S. Nuclear Regulatory Commission, Code of Federal Regulations, Title 10, Parts 20 and 40.

f. U.S. Nuclear Regulatory Commission, Branch Technical Position, "Disposal or Onsite Storage of Thorium or Uranium Wastes from Past Operations," Federal Register, Vol 46 No. 205, October 23, 1981.

g. ICF Kaiser Engineering, Inc., "30% Temporary Thorium Storage Structure Design Report," dated May 13, 1996.

h. ICF Kaiser Engineers, Inc., "Design Basis Document Temporary Thorium Storage Structure," dated July 10, 1996.

i. ICF Kaiser Engineers, Inc., "Final Design Report Temporary Thorium Storage Structure," dated August, 1995.

ATTACHMENT 3

DRAFT

TOXICOLOGICAL PROFILE FOR THORIUM

Prepared by:

Syracuse Research Corporation
Under Subcontract to:

Clement Associates, Inc.
Under Contract No. 205-88-0608

Prepared for:

Agency for Toxic Substances and Disease Registry
U.S. Public Health Service

In collaboration with:

U.S. Environmental Protection Agency

October 1990

Toxicological Profile for

THORIUM

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry

TP-90-25

TABLE 1-3. Human Health Effects from Eating or Drinking Thorium*

Short-term Exposure (less than or equal to 14 days)		
Levels in Food	Length of Exposure	Description of Effects
		The health effects resulting from short-term exposure of humans to food containing specific levels of thorium are not known.
Levels in Water		The health effects resulting from short-term exposure of humans to drinking water containing specific levels of thorium are not known.
Long-term Exposure (greater than 14 days)		
Levels in Food	Length of Exposure	Description of Effects
		The health effects resulting from long-term exposure of humans to food containing specific levels of thorium are not known.
Levels in Water		The health effects resulting from long-term exposure of humans to drinking water containing specific levels of thorium are not known.

*See Section 1.2 for a discussion of exposures encountered in daily life.

TABLE 1-4 Animal Health Effects from Eating or Drinking Thorium

Short-term Exposure (less than or equal to 14 days)		
Levels in Food	Length of Exposure	Description of Effects*
		The health effects resulting from short-term exposure of animals to food containing specific levels of thorium are not known.
Levels in Water (ppm)		
3900	One dose	Death in mice.
Long-term Exposure (greater than 14 days)		
Levels in Food	Length of Exposure	Description of Effects*
		The health effects resulting from long-term exposure of animals to food containing specific levels of thorium are not known.
Levels in Water (ppm)		
1000	4 months	Death in mice.

*These effects are listed at the lowest level at which they were first observed. They may also be seen at higher levels.

2. HEALTH EFFECTS

2.1 INTRODUCTION

This chapter contains descriptions and evaluations of studies and interpretation of data on the health effects associated with exposure to thorium. Its purpose is to present levels of significant exposure for thorium based on toxicological studies, epidemiological investigations, and environmental exposure data. This information is presented to provide public health officials, physicians, toxicologists, and other interested individuals and groups with (1) an overall perspective of the toxicology of thorium and (2) a depiction of significant exposure levels associated with various adverse health effects.

2.2 DISCUSSION OF HEALTH EFFECTS BY ROUTE OF EXPOSURE

To help public health professionals address the needs of persons living or working near hazardous waste sites, the data in this section are organized first by route of exposure -- inhalation, oral, and dermal -- and then by health effect -- death, systemic, immunological, neurological, developmental, reproductive, genotoxic, and carcinogenic effects. These data are discussed in terms of three exposure periods -- acute, intermediate, and chronic.

Levels of significant exposure for each exposure route and duration (for which data exist) are presented in tables and illustrated in figures. The points in the figures showing no-observed-adverse-effect levels (NOAELs) or lowest-observed-adverse-effect levels (LOAELs) reflect the actual levels of exposure used in the studies. LOAELs have been classified into "less serious" or "serious" effects. These distinctions are intended to help the users of the document identify the levels of exposure at which adverse health effects start to appear, determine whether or not the intensity of the effects varies with dose and/or duration, and place into perspective the possible significance of these effects to human health.

The significance of the exposure levels shown on the tables and figures may differ depending on the user's perspective. For example, physicians concerned with the interpretation of clinical findings in exposed persons or with the identification of persons with the potential to develop such disease may be interested in levels of exposure associated with "serious" effects. Public health officials and project managers concerned with response actions at Superfund sites may want information on levels of exposure associated with more subtle effects in humans or animals (LOAEL) or exposure levels below which no adverse effects (NOAEL) have been observed.

Thorium is a relatively reactive, metallic radioactive element. Because thorium is a radioactive element, evaluation of adverse health effects due to exposure to thorium requires a slightly different approach than with chemicals. Radiation is a health risk because radioactive elements can emit energetic particles or electromagnetic radiation that can damage cells. Radioactive elements are those that undergo spontaneous

disintegration (decay) in which energy is released (emitted) either in the form of particles, such as alpha or beta particles, or rays, such as gamma or x-rays. This disintegration or decay results in the formation of new elements, some of which may themselves be radioactive, in which case they will also decay. The process continues until a stable (non-radiative) state is reached (see Appendix B for more information). The rate of emission of alpha particles from thorium is low, and the rate of emission of gamma rays is very low (see Chapter 3). Alpha particles are unable to deeply penetrate skin, but can travel short distances in the body (about 4 to 6 cell diameters) if they are emitted from within the body. The intensity and energy of alpha particles emitted depends on the particular isotope of thorium in question. Several isotopes of thorium exist. By mass, the most predominant ones in the environment are thorium-230 (a decay product of uranium-238) and natural thorium (thorium-232) (see Chapter 3). The number of particles emitted is related to the radioactive half-life of the isotope, which is about 14 billion years for natural thorium (thorium-232). The other type of radiation hazard is from gamma rays, which can penetrate the body and pass through the air. However, natural thorium has a very low gamma activity, which means there is little danger from this type of radiation from natural thorium. Daughter products of thorium, however, may emit more gamma radiation than natural thorium (see Chapter 3).

When thorium emits alpha particles, it disintegrates into other daughter radionuclides (radioactive materials), such as radium-226 and radon-222 (from thorium-230 in the uranium-238 decay series) or radium-228 and thoron (radon-220 from thorium-232 in the thorium decay series). It eventually decays to stable lead-208 or -206, which is not radioactive. More information about the decay of thorium can be found in Chapter 3. The toxicological characteristics of radon, radium, and lead are the subject of separate ATSDR Toxicological profiles.

The decay rate or activity of radioactive elements has traditionally been specified in curies (Ci). The curie is approximately 37 billion disintegrations (decay events) per second (3.7×10^{10} dps). In discussing thorium, a smaller unit, the picocurie (pCi) is used, where pCi is equal to 1×10^{-12} Ci. In international usage, the S.I. unit (the International System of Units) for activity is the Becquerel (Bq), which is equal to 1 disintegration per second or about 27 pCi. (Information for conversion between units is given in Appendix B.) Measurements of radioactivity, expressed as nCi (nanocurie), in the environment are more sensitive than units of mass. For this reason, amounts of thorium are expressed in pCi units in Chapter 5. In animal studies, the exposure levels were usually reported in mg (milligrams), but have been converted to activity units (nCi and Bq) for presentation in Chapter 2. The absorbed dose from radiation can be expressed in units of rads or it can be stated in terms of dose equivalent, which includes a modification to reflect the quality of the radiations, for radiation protection purposes, and is expressed in terms of rems. For alpha radiations a quality factor, Q, of 20 is used to convert absorbed dose to dose equivalent.

2. HEALTH EFFECTS

Both large and small amounts of radiation are damaging to health. Current scientific consensus is radiation can also increase the probability of cancer, and a conservative assumption is no threshold level exists below which there is no additional risk of cancer. There is considerable debate about how great the cancer risks are when people are chronically exposed to very low levels of radiation. Since everyone is environmentally exposed to a small amount of radiation, the minimum amount of additional radiation that may constitute a health hazard is not well known.

The following sections summarize the health effects associated with thorium. Evidence exists that most, if not all, effects of thorium may be due to its radiological, and not chemical, effects. The mechanism of toxicity for all effects are not well understood. For more information about radiation, see Appendix B.

2.2.1 Inhalation Exposure

2.2.1.1 Death

Two epidemiology studies have examined mortality among thorium workers; neither found significant excess mortality. The standard mortality ratio (SMR) for all causes of death in a cohort of 3039 male workers in a thorium processing plant was 1.05 in comparison to United States white males (Polednak et al. 1983). The estimated radiation levels to the workers for inhalation intake ranged from 0.003-0.192 nCi/m^3 (0.001-0.007 Bq/m^3) for a period of 1-33 years. No evidence of overt industrial disease was found in a cohort of 84 workers at a thorium refinery exposed to <0.045-450 nCi/m^3 (<0.002-0.02 Bq/m^3) for <1-20 years (Albert et al. 1955). In both studies, the workers were exposed to other toxic compounds (uranium dust) as well as other radioactive materials (thoron, uranium daughters, thorium daughters, cerium).

No compound-related mortality was found in mice exposed to 114-330 mg/m^3 (12.54-36.3 nCi/m^3 = 464-1343 Bq/m^3) thorium nitrate intermittently for 18 weeks (Patrick and Cross 1948). No compound-related mortality was found in rats, guinea pigs, rabbits, or dogs exposed intermittently for 1 year to 5 mg thorium/m^3 (0.550 nCi/m^3 = 20 Bq/m^3) as thorium dioxide (Hodge et al. 1960). These NOAEL values are reported in Table 2-1 and plotted in Figure 2-1.

2.2.1.2 Systemic Effects

Respiratory Effects. Although the SMR for respiratory diseases was 1.31 among workers at a thorium refinery (Polednak et al. 1983), the increase may have been attributable in part to smoking. Exposure level estimates for inhalation intakes ranged from 0.003-0.192 nCi/m^3 (0.001-0.007 Bq/m^3) for a period of 1-33 years. Because the workers were exposed to

TABLE 2-1. Levels of Significant Exposure to Thorium - Inhalation

Figure Key	Species	Exposure Frequency/ Duration	Effect	NOAEL (nCi/m^3)	LOAEL (Effect) Less Serious (nCi/m^3)	LOAEL (Effect) Serious (nCi/m^3)	Reference	Chemical Form
INTERMEDIATE EXPOSURE								
Death								
1	Mouse	18 weeks 5 days/week 40 minutes/day		36.3			Patrick and Cross 1948	$ThNO_3$
Systemic								
2	Dog	304 days 5 days/week 6 hours/day	Hemato		0.9[a] (decreased RBC)		Hall et al. 1951	TF_4
CHRONIC EXPOSURE								
Death								
3	Rat	14 months 5 days/week 6 hours/day		0.55			Hodge et al. 1960	ThO_2
4	Gn Pig	14 months 5 days/week 6 hours/day		0.55			Hodge et al. 1960	ThO_2
5	Rabbit	14 months 5 days/week 6 hours/day		0.55			Hodge et al. 1960	ThO_2
6	Dog	14 months 5 days/week 6 hours/day		0.55			Hodge et al. 1960	ThO_2
Systemic								
7	Rat	14 months 5 days/week 6 hours/day	Resp Hemato Musc/skel Hepatic Renal	0.55 0.55 0.55 0.55 0.55			Hodge et al. 1960	ThO_2

TABLE 2-1 (Continued)

Figure Key	Species	Exposure Frequency/ Duration	Effect	NOAEL (nCi/m^3)	LOAEL (Effect) Less Serious (nCi/m^3)	LOAEL (Effect) Serious (nCi/m^3)	Reference	Chemical Form
8	Gn Pig	14 months 5 days/week 6 hours/day	Resp Hemato Musc/skel Hepatic Renal	0.55 0.55 0.55 0.55 0.55			Hodge et al. 1960	ThO_2
9	Rabbit	14 months 5 days/week 6 hours/day	Resp Hemato Musc/skel Hepatic Renal	0.55 0.55 0.55 0.55 0.55			Hodge et al. 1960	ThO_2
10	Dog	14 months 5 days/week 6 hours/day	Resp Hemato Musc/skel Hepatic Renal	0.55 0.55 0.55 0.55 0.55			Hodge et al. 1960	ThO_2

[a]The mg/m^3 equivalent of 0.9 nCi/m^3 is 8.3 mg/m^3. This value is converted to an equivalent concentration of 1.8 ppm for presentation in Table 1-2.

Gn Pig = guinea pig; Hemato = hematological; LOAEL = lowest-observed-adverse-effect level; Musc/skel = muscular/skeletal; NOAEL = no-observed-adverse-effect level; RBC = red blood cell; Resp = respiratory; TF_4 = thorium tetrafluoride; $ThNO_3$ = thorium nitrate; ThO_2 = thorium dioxide.

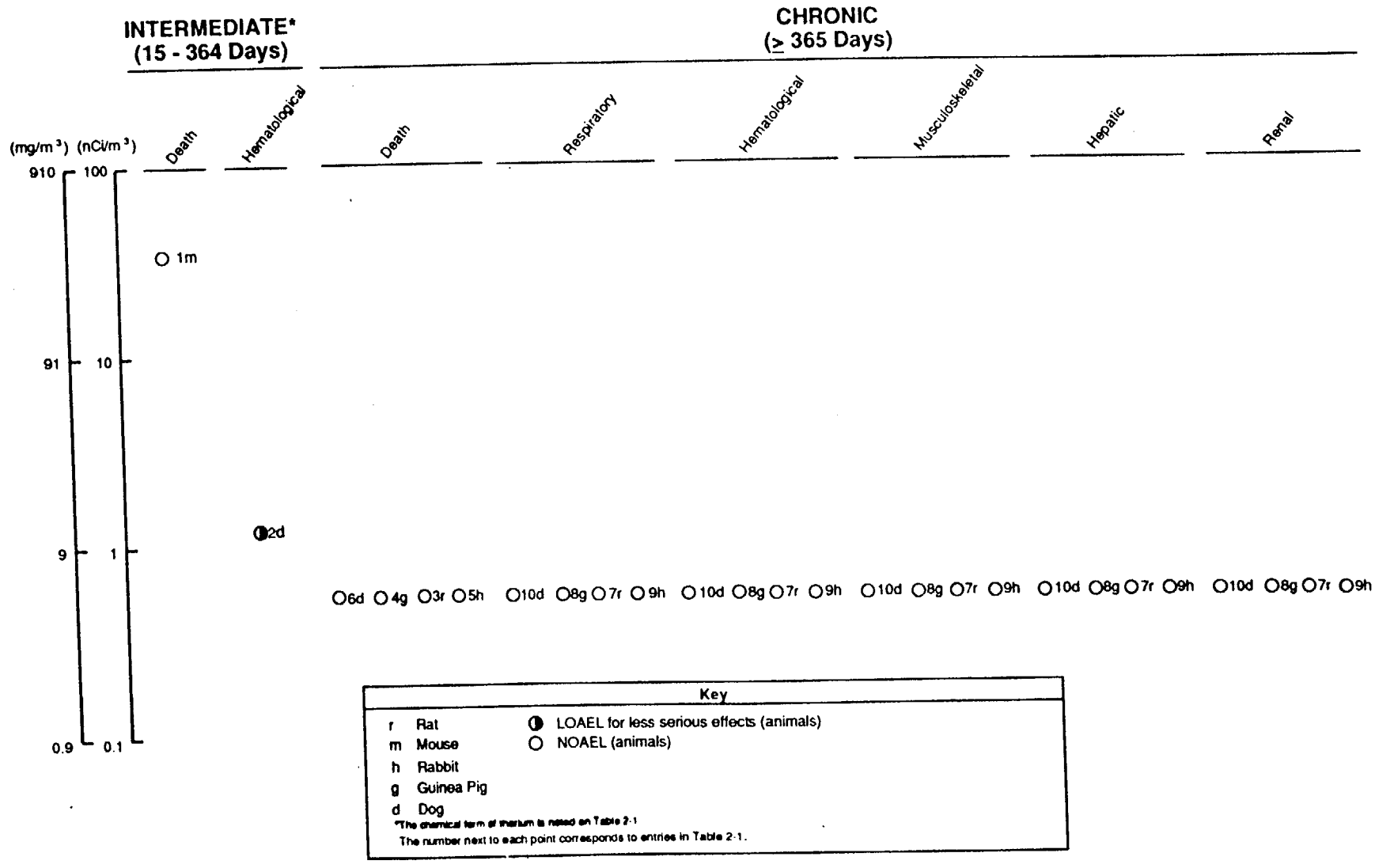


FIGURE 2-1. Levels of Significant Exposure to Thorium - Inhalation

other toxic compounds (uranium dust) as well as other radioactive metals, toxic effects cannot necessarily be attributed to thorium. Therefore, no quantitative information from the study is reported in Table 2-1 or Figure 2-1.

Progressive cirrhosis of the lungs was found in a subchronic inhalation study in rats (Likhachev et al. 1973a). Rats were exposed intermittently for 6-9 months to an inert aerosol (control), to the inert aerosol enriched with 10% or 49% insoluble thorium dioxide, or to thorium dioxide (100%) alone. The severity of the lung cirrhosis was directly related to the radiation dose and the amount of thorium dioxide. Cirrhosis of the lungs became evident in 3-6 months in the 100% thorium dioxide group, in 9-12 months in the 49% thorium dioxide group, in 12-15 months in the 10% thorium dioxide group, and in 18-24 months in the inert aerosol control group. At lung exposures of up to 150 rad, reticulosarcoma was found, while at lung exposures of 100-2700 rad, glandular cancerous tumors were found (see Section 2.2.1.8). The tumors may have been caused by thorium dioxide; the exact amount of thorium administered was not clear from the report, so the results of the study do not appear in Table 2-1 or Figure 2-1.

No histopathological effects on the lungs were found in rats, guinea pigs, rabbits, or dogs exposed intermittently for 1 year to 5 mg thorium/m^3 (0.550 nCi/m^3 = 20 Bq/m^3) as thorium dioxide (Hodge et al. 1960). This NOAEL value is presented in Table 2-1 and plotted in Figure 2-1.

Hematological Effects. A complete blood count (CBC) was done on a cohort of 273 male monazite sand refinery workers to determine the effect of thorium on the hematological system. The measured body burden (calculated from <u>in vivo</u> detection of external gamma rays emitted by daughter products of thorium still in the subject's body and from thoron in expired air) of thorium was higher in those workers exposed for a longer time period, but the blood count did not correlate with the body burden of thorium (Conibear 1983). A correlation was found, however, between the blood count and cigarette smoking habits. Exposure level estimates for inhalation intakes of nicotine or thorium were not reported, and the external gamma-ray exposure rate was between 0.5 and 5.0 mR/hour. Because the workers were exposed to other toxic compounds (silica, yttrium, acid and alkali fumes) as well as other sources of radioactivity, toxic effects cannot necessarily be attributed to thorium. Therefore, the results of the study do not appear in Table 2-1 or Figure 2-1.

Effects on hematological parameters (abnormal forms of monocytes, lymphocytes and granulocytes, hypoplastic bone marrow, red cell count depression, macrocytosis, increase in immature granulocytes) were found in dogs exposed 6 hours/day, 5 days/week to various chemical forms of thorium: thorium nitrate tetrahydrate for 60 days (4 nCi/m^3 = 150 Bq/m^3); thorium dioxide for 60 days (4.8 nCi/m^3 = 180 Bq/m^3); thorium tetrafluoride for 304 days (0.9 nCi/m^3 = 33 Bq/m^3); thorium oxalate for 270 days (1.4 nCi/m^3 = 52 Bq/m^3) (Hall et al. 1951). Differences in the degree of toxicity of the

various chemical forms of thorium on hematological parameters could not be determined from this study, although gagging, retching, and occasional vomiting were found periodically in the dogs exposed to thorium nitrate tetrahydrate. The lowest LOAEL, thorium tetrafluoride (0.9 nCi/m^3 = 33 Bq/m^3), is reported on Table 2-1 and plotted on Figure 2-1.

No effects on hematological parameters, blood nonprotein nitrogen (NPN), or the histopathology of the spleen were found in rats, guinea pigs, rabbits, or dogs exposed for 1 year to 5 mg/thorium m^3 (0.550 nCi/m^3 = 20 Bq/m^3) as thorium dioxide (Hodge et al. 1960). This NOAEL value is presented in Table 2-1 and plotted in Figure 2-1.

Musculoskeletal Effects. No studies were located regarding the musculoskeletal effects in humans after inhalation exposure to thorium.

Upon histopathological examination, no effects in the femur were found in rats, guinea pigs, rabbits, or dogs exposed for 1 year to 5 mg thorium/m^3 (0.550 nCi/m^3 = 20 Bq/m^3) as thorium dioxide (Hodge et al. 1960). This NOAEL value is presented in Table 2-1 and plotted in Figure 2-1.

Hepatic Effects. The levels of aspartate aminotransferase, globulin, and total bilirubin in sera of a cohort of 275 former workers in a thorium refinery were correlated with body burdens of radioactivity (Farid and Conibear 1983). The levels of aspartate aminotransferase and total bilirubin were significantly higher ($p<0.0001$ and $p=0.043$, respectively) in thorium-exposed workers, as compared to U.S. white males. Globulin levels also increased with increasing levels of body burden, but not significantly. Although the enzymatic levels tested were elevated, they were still within the normal range. No effects on albumin, total protein, or alkaline phosphatase were seen. The correlation of hepatic function tests with body burden of radioactivity may suggest a radiotoxic effect, but this was not proven by the authors. No exposure concentrations were reported.

No histopathological effects in the liver were found in rats, guinea pigs, rabbits, or dogs exposed to 5 mg thorium/m^3 (0.550 nCi/m^3 = 20 Bq/m^3) for 1 year as thorium dioxide (Hodge et al. 1960). This NOAEL value is presented in Table 2-1 and plotted in Figure 2-1.

Renal Effects. No studies were located regarding renal effects in humans after inhalation exposure to thorium.

No histopathological effects in the kidneys were found in rats, guinea pigs, rabbits, or dogs exposed to 5 mg thorium/m^3 (0.550 nCi/m^3 = 20 Bq/m^3) for 1 year as thorium dioxide (Hodge et al. 1960). This NOAEL value is presented in Table 2-1 and plotted in Figure 2-1.

2.2.1.3 Immunological Effects

No studies were located regarding immunological effects in humans after inhalation exposure to thorium.

No histopathological effects in the lymph nodes were found in rats, guinea pigs, rabbits, or dogs exposed to 5 mg thorium/m^3 (0.550 nCi/m^3 = 20 Bq/m^3) for 1 year as thorium dioxide (Hodge et al. 1960). Since no parameters of immune function were examined, this value does not appear as a NOAEL for immunological effects in Table 2-1 or Figure 2-1.

No studies were located regarding the following health effects in humans or animals after inhalation exposure to thorium.

2.2.1.4 Neurological Effects

2.2.1.5 Developmental Effects

2.2.1.6 Reproductive Effects

2.2.1.7 Genotoxic Effects

Hoegerman and Cummins (1983) assessed the frequency of chromosome aberrations in the lymphocytes of 47 male workers in a thorium processing plant. The workers were divided into three groups based on their body burdens of radioactivity: low (0 nCi/kg), moderate (0.003 nCi/kg = 0.11 Bq/kg), and high (0.015 nCi/kg = 0.56 Bq/kg) body burden groups. An increased frequency of chromosomal aberrations (dicentric ring chromosomes) were found in the high burden groups (combined high and moderate burden groups) compared to the low burden group and historical controls. No significant differences were found in the frequency of two-break chromosome aberrations. A positive correlation was not established between the frequency of chromosomal aberrations and duration of employment. The observed aberration frequency was generally compatible with that found in patients injected with thorium dioxide colloid (Thorotrast) (see Section 2.2.4.7). Costa-Ribeiro et al. (1975) also reported a statistically significant ($p<0.05$) increase in the number of chromosomal aberrations (dicentrics) in 240 monazite sand millers, as compared to controls. No significant differences in the incidence of translocations were observed. No exposure concentrations were reported in either study.

No studies were located regarding genotoxic effects in animals after inhalation exposure to thorium.

2.2.1.8 Cancer

A statistically significant excess of deaths from pancreatic cancer was seen in a cohort of 3039 former thorium workers employed for 1 year or more (6 observed vs. 1.3 expected) but not in workers employed for a shorter time

(3 observed vs. 2.7 expected) (Stehney et al. 1980). The workers were exposed to 0.003-0.192 nCi/m^3 (0.001-0.007 Bq/m^3). Although a correlation between smoking and pancreatic cancer has not been established, the excess mortality may be due, in part, to the fact that a higher proportion of smokers was found in the worker population when compared to U.S white males (ratio of 1.3 observed smokers/expected smokers). A second study compared the SMR of workers in a thorium processing plant to the mortality rates for U.S. white males and determined that the SMRs in the workers were high for deaths due to lung cancer (SMR=1.44; 95% confidence limit 0.98 and 2.02) and pancreatic cancer (SMR=2.01; 95% confidence limit 0.92 and 3.82) (Polednak et al. 1983). In a subgroup of men in jobs with the highest exposure to thorium, the SMR for lung cancer was 1.68 and the SMR for pancreatic cancer was 4.13. Exposure level estimates for inhalation intakes ranged from 0.003-0.192 nCi/m^3 (0.0001-0.007 Bq/m^3) for a period of 1-33 years. The authors indicated that smoking may be a confounding factor in the increased rates of cancer and that the workers were exposed to other potentially carcinogenic agents, such as thoron (radon-220). Consequently, the evidence for a causal relationship between thorium exposure and cancer is not convincing and no concentrations are reported in Table 2-1 or plotted in Figure 2-1.

A significantly ($p<0.05$) increased incidence of malignancies in the lymphatic and hematopoietic tissues of uranium mill workers (cohort of 662 males) was found by Archer et al. (1973). The radioactivity in the tracheobronchial lymph nodes of the workers was found to be primarily the result of alpha emissions from thorium-230 and not from uranium-234 or uranium-238. Consequently, the authors suggested that the increased incidence of malignancies may have been a result of thorium-230 exposure and not uranium exposure. Exposure levels of thorium were not reported; therefore, the results of the study are not reported on Table 2-1 or plotted in Figure 2-1.

Rats were exposed to various concentrations of thorium dioxide for 6-9 months, and the frequency and histological type of lung tumors were determined following observation for up to 21 months (Likhachev et al. 1973b; Likhachev 1976). The authors concluded that the incidence and histological type of lung tumors that developed were dependent on the radiation dose to the lungs. At lung doses of up to 150 rad (3000 rems), primarily reticulosarcoma was found (in 16% of the animals), while at total doses of 1000-2700 rads (20,000-54,000 rems), glandular cancerous tumors (adenomatosis and squamous cell carcinoma) were found in all of the exposed animals, and the reticulosarcoma was no longer observed.

2.2.2 Oral Exposure

2.2.2.1 Death

No studies were located regarding lethal effects in humans after oral exposure to thorium.

A single gavage administration of 1000 mg thorium/kg body weight/day (110 nCi/kg/day = 4070 Bq/kg/day) as thorium nitrate resulted in the death of 4/20 mice, while a single amount of 760 mg thorium/kg body weight/day (84 nCi/kg/day = 3100 Bq/kg/day) resulted in no mortality. Occasional intestinal hemorrhage was noted at autopsy in the mice that died, but it was not reported if the hemorrhage was the cause of death in the animals. No effects were found following administration of a 10% sodium nitrate solution, suggesting that the adverse effects were due to thorium and not to nitrate (Patrick and Cross 1948). Following 4 months of continuous exposure to 123 mg thorium/kg body weight/day (13.6 nCi/kg/day = 503 Bq/kg/day) as thorium nitrate in the drinking water, 50% of the treated mice and 10% of the control mice died (Patrick and Cross 1948). No cause of death was reported in either the acute or the 4-month studies. In rats, 4 months of exposure to 3043 mg thorium/kg body weight/day (335 nCi/kg/day = 12,400 Bq/kg/day) as thorium nitrate resulted in death, but the deaths may have been due to the poor nutritional state of the animals since the treated animals ate much less of the treated food and, therefore, lost weight (Downs et al. 1959).

Death occurred following four daily administrations of ≥2130 mg thorium/kg body weight/day (234 nCi/kg/day = 8657 Bq/kg/day) as thorium nitrate in the food to a single dog (Patrick and Cross 1948). No immediate deaths were reported following a single administration of 121 mg thorium/kg body weight/day (13 nCi/kg/day = 481 Bq/kg/day) by gavage as thorium nitrate to dogs (Sollman and Brown 1907). Death was not found following exposure of a single dog to food containing 426 mg thorium/kg body weight/day (47 nCi/kg/day = 1740 Bq/kg/day) as thorium nitrate for 46 days (Downs et al. 1959). No deaths were reported following a single gavage administration of thorium nitrate (483 mg thorium/kg body weight/day = 53 nCi/kg/day = 1960 Bq/kg/day) in rabbits (Sollman and Brown 1907). The number of treated and control animals (dogs and rabbits) was not reported in the Sollman and Brown (1907) study.

All reliable NOAEL and LOAEL values are reported in Table 2-2 and plotted in Figure 2-2. Values from the Sollman and Brown (1907) study are not reported in the table and figure since the number of animals in the study were not reported. The LOAEL value for death in rats from the Downs et al. (1959) study is not reported since the deaths may have been due to the poor nutritional state of the animals and not to thorium toxicity, and the NOAEL and LOAEL values for the death of dogs in the Downs et al. (1959) and the Patrick and Cross (1948) studies, respectively, are not reported since they were pilot studies and only one animal was used.

2.2.2.2 Systemic Effects

Respiratory Effects. No studies were located regarding the respiratory effects in humans after oral exposure to thorium.

TABLE 2-2. Levels of Significant Exposure to Thorium - Oral

Figure Key	Species	Route	Exposure Frequency/ Duration	Effect	NOAEL (nCi/kg/day)	LOAEL (Effect) Less Serious (nCi/kg/day)	LOAEL (Effect) Serious (nCi/kg/day)	Reference	Chemical Form
ACUTE EXPOSURE									
Death									
1	Mouse	(G)	1 day		84		110[a] (4/20)	Patrick and Cross 1948	$ThNO_3$
INTERMEDIATE EXPOSURE									
Death									
2	Mouse	(W)	4 months 7 days/week 24 hours/day				12[b] (10/20)	Patrick and Cross 1948	$ThNO_3$
Systemic									
3	Rat	(F)	4 months 7 days/week 24 hours/day	Resp Cardio Gastro Hemato Hepatic Renal	335 335 335 335 335 335			Downs et al. 1959	$ThNO_3$
Reproductive									
4	Rat	(F)	4 months 7 days/week 24 hour/day		335			Downs et al. 1959	$ThNO_3$

[a]The mg/kg equivalent of 110 nCi/kg = 1000 mg/kg. This value is converted to an equivalent concentration of ppm in water for presentation in Table 1-4.
[b]The concentration in drinking water was 0.1%. This equals 1000 mg/L = 1000 ppm. This concentration is presented in Table 1-4.

(G) = gavage; Cardio = cardiovascular; (F) = food; Gastro = gastrointestinal; Hemato = hematological; LOAEL = lowest-observed-adverse-effect level; NOAEL = no-observed-adverse-effect level; Resp = respiratory; $ThNO_3$ = thorium nitrate; (W) = water.

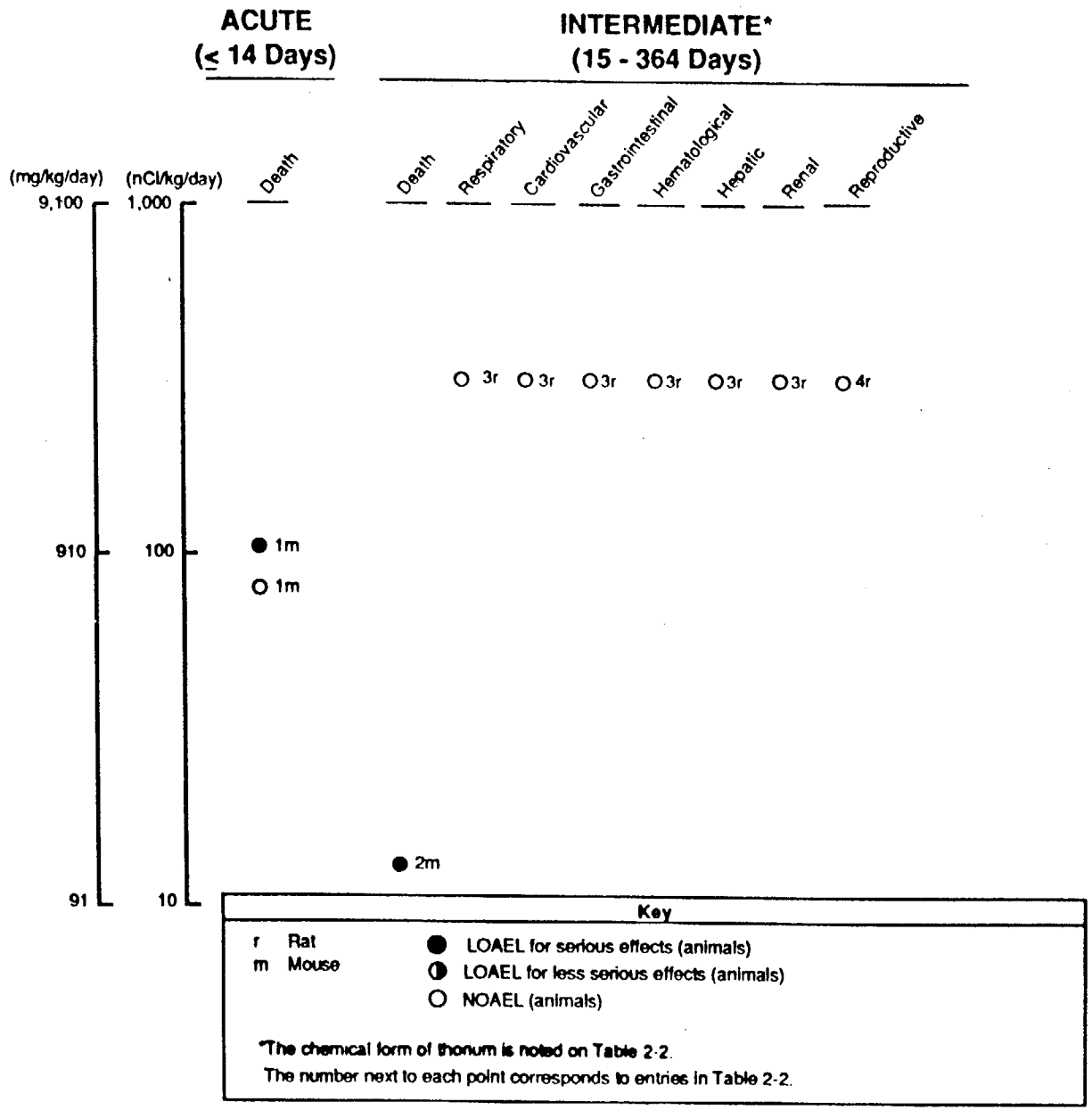


FIGURE 2-2. Levels of Significant Exposure to Thorium - Oral

ATTACHMENT 4

Radiation Protection Dosimetry

BECQUEREL'S LEGACY: A CENTURY OF RADIOACTIVITY

Proceedings of a Conference
London, February 29 & March 1 1996

Proceedings Editor:

M.C. O'Riordan

ISBN 1 870965 47 7
CONF 9602119
RADIATION PROTECTION DOSIMETRY
Published by Nuclear Technology Publishing **Vol. 68 Nos. 1/2 1996**

Radiation Protection Dosimetry
Vol. 68, No. 1/2, pp. 97–103 (1996)
Nuclear Technology Publishing

EPIDEMIOLOGICAL EVIDENCE OF HAZARD

R. Doll
ICRF/MRC/BHF Clinical Trial Service Unit and Epidemiological Studies Unit
Harkness Building, Radcliffe Infirmary, Oxford OX2 6HE, UK

Abstract — Epidemiological evidence of the long-term effects of exposure to radionuclides is limited to the production of cancer. For most radionuclides of medical or social interest the numbers of people exposed have been too few or the doses have been too small for the observed risks to have statistical stability. Useful data are available only for thorium (from the use of Thorotrast), radium (from the medicinal use of ^{224}Ra), radon (from the occupational exposure of 11 groups of miners) and radioiodine (from its use in the treatment of thyroid cancers and thyrotoxicosis and its release in nuclear accidents). The findings suggest that prediction from the knowledge of the effects of moderate doses of low LET radiation with current assumptions about the radiation weighting factor for alpha radiation and the reduction in risk with low dose rates is not far out, although in some instances the weighting factor may be too high or the dose rate reduction factor too low.

INTRODUCTION

Epidemiological evidence of the long-term effects of alpha and beta radiation is limited to the production of cancer. Much exists, but its use to quantify risks in terms of grays or sieverts is exceptionally hard: for alpha and beta radiation penetrate biological tissue only up to 0.05 and 2 mm respectively, so that we have to know precisely where the radionuclides are deposited and their proximity to the stem cells that are capable of giving rise to the disease, before the relevant doses can be estimated.

For many radionuclides, the numbers of people exposed have been too few, or the doses too small, for the observed risks to have statistical stability. These include plutonium, uranium, and polonium, radioactive isotopes of iron, sulphur, and phosphorus, and the radioactive isotopes of caesium and strontium that were the principal components of the global fallout from the testing of nuclear weapons between 1954 and 1966. The available data have been reviewed by the United Nations Scientific Committee on the Effects of Atomic Radiation[1]. None provides any worthwhile estimate of risk, except in so far as the observations on childhood leukaemia in Utah following the testing of nuclear weapons in Nevada[2] and in the Nordic countries following the worldwide testing of nuclear weapons in the early 1960s[3] have excluded the possibility that the risks are much greater than those estimated by extrapolation from the effects of low LET radiation and the use of weighting factors derived from animal experiments to convert grays to sieverts. Useful quantitative information has, however, been obtained about the hazards of exposure to thorium, radium, radon, and radioactive iodine and my review is confined to them.

THORIUM

Very few people are now exposed to thorium and those that are, in the extraction of thorium from monazite sands and the manufacture of magnesium alloys and photoelectric cells for measuring ultraviolet light, are exposed to such small amounts that no increased risk should be detectable. Many patients were, however, exposed to substantial doses when injected with Thorotrast, a 25% colloidal solution of thorium dioxide that was sometimes used as a contrast agent for angiography between 1930 and 1955. Thorium decays through a series of alpha-emitting radionuclides with a half-life of 1.4×10^{10} y and Thorotrast is excreted so slowly that the biological half-life is 700 y. Patients were, therefore, effectively irradiated with alpha particles at a constant rate for the rest of their lives.

A standard injection has an alpha particle activity of 1.8×10^4 Bq, nearly 60% of which was concentrated in the liver. As a result, 618 patients developed liver cancer out of nearly 5000 given such injections and subsequently followed up in Denmark, Germany, Japan and Portugal. The best data are those for the Danish series reported by Andersson and Storm[4]. In 999 patients exposed in the course of cerebral angiography between 1935 and 1947 and followed to 1.1.1989, the risk of liver cancer was increased over 100 times (95% confidence limits 100 to 157 times). Leukaemia was increased tenfold (95% confidence limit 6.5 to 15 times) and all other cancers in combination were more than doubled, the excess being spread over many types including myeloma and cancers of the gallbladder, peritoneum, and lung.

Estimation of the doses received in different organs is exceptionally difficult, as the colloid material rapidly became granular, was phagocytised, and collected in aggregates of up to 100 μm in radius, so that much of the alpha irradiation was absorbed within the aggregates. Estimates of the cumulative risks of liver cancer and leukaemia made by the US National Research Council[5] were similar per unit dose for the German, Japanese, and Portuguese studies. They are shown in Table 1 on the assumption of a weighting factor for alpha radiation of 20 along with the corresponding estimates for low dose rate low LET radiation made respectively by UNSCEAR[1] and the International

Commission on Radiological Protection[6]. Whether the alpha radiation should be thought to have been received at a low rate is, perhaps, open to question, yet even compared with low dose rate low LET radiation the risk is materially smaller and substantially so in the case of leukaemia. The comparison is, however, only tentative at the best, because of the difficulty of estimating the tissue dose from Thorotrast and allowing for any cell-killing effect and possible secondary effect of the associated cirrhosis. Moreover, the thorium data are limited to adults, while the risk attributed to low LET radiation is for all ages. What is not tentative, is the scale of the tragedy caused by the use of Thorotrast. According to Trott[7] some 10,000 of the 100,000 patients given Thorotrast worldwide may have died from radiation-induced cancer: that is, 10 times the number thought to have died from radiation-induced cancer among the survivors of the atomic bomb explosions in Japan.

RADIUM

The discovery of the disastrous effect of the uncontrolled use of radium by young women who applied a paint made luminous by the addition of small amounts of ^{226}Ra and ^{228}Ra in a factory in New Jersey in the 1920s has been described by Professor Lindell. Now, more than 60 years later, bone sarcomas are known to have occurred in 85 of nearly 5000 men and women occupationally or therapeutically exposed to these isotopes in the United States before 1950. Among the 2403 for whom an estimate of the skeletal dose has been made, 64 have developed bone sarcomas when less than 2 would have been expected[5]. Only one other type of cancer has been identified in excess among them: namely, carcinoma of the paranasal sinuses and mastoid air cells which normally occurs with about the same frequency as bone sarcoma. Some 35 such cancers have occurred in 31 individuals, caused by radon produced as a decay product being trapped in confined air spaces. Leukaemia, which might have been expected to be produced, does not seem to have occurred in excess, as only 10 cases have been diagnosed in the luminous dial painters against an expected number of 9[8]. A few cases may, however, have been overlooked in the early days, when aleukaemic leukaemia tended to be diagnosed as anaemia[9].

Examination of the dose–response relationship is unrewarding, because of uncertainty about the initial doses, and about the distribution of radium within the bone, some of which is likely to have been aggregated in hot spots with a consequent disproportionate amount of cell killing. Much more useful information can be obtained from the study of 900 German patients who were given repeated injections of a short-lived isotope of radium (^{224}Ra) in the treatment of bone tuberculosis, ankylosing spondylitis, and a few other conditions shortly after the second world war. On average 0.67 $MBq.kg^{-1}$ were injected over periods that varied from 1 to 45 months, leading to an average skeletal dose of just over 4 Gy[10]. Young people under 20 years of age received nearly twice the amount per kg as older people and, as uptake is enhanced in growing bone, the dose to the endosteal surface in juveniles was 5 times that in adults (10.6 Gy against 2.1 Gy).

Among these 900 patients, 54 have developed bone sarcomas against an expected number of less than 1 (0.2). The first tumour appeared after $3\frac{1}{2}$ years, the peak incidence was after 6–8 years, and only one tumour has so far appeared in the last 10 years, 33 years after exposure[11]. The incidence has not varied with the patient's age; but it has with dose and the duration of treatment. Relatively more cases were produced when duration was prolonged, which could have resulted from greater cell killing, when relatively large amounts were given on a few occasions, or from a greater number of dividing cells being at risk when the duration of treatment was prolonged, because of the greater opportunity for cell regeneration between injections. The best fitting model for the dose–response relationship is shown in Table 2[12]. The data fit the model well and provide no reason to postulate a threshold below which no effect would be produced.

The findings lead to an estimate of a lifetime risk of bone cancer of about 150×10^{-4} Gy^{-1} and of fatal bone cancer of about 100×10^{-4} Gy^{-1}[5]. No useful comparison can be made with exposure to low LET radiation, as observations have not been made on sufficient numbers of cases to provide reliable quantitative estimates of risk. The few that have been reported suggest somewhat lower risks[1] even if alpha radiation is given a weighting factor of 20.

Table 1. Comparative risks from thorium and external low LET radiation (Refs 1 and 5).

Type of cancer	Lifetime cumulative risk 10^{-4} Sv^{-1}	
	^{232}Th*	External low LET
Liver cancer	15	60
Leukaemia	3	50

*Weighting factor for alpha radiation assumed to be 20.

Table 2. Dose–response relationship: radium and bone sarcoma (after Chmelevsky *et al*[12]).

R(D,t)	= 0.0055D (1 + 0.18t)
R(D,t)	= proportion affected
D	= average skeletal dose in grays
t	= period of delivery in months

RADON

The principal interest of the evidence relating to thorium and radium is now, perhaps, the light it throws on the relative risks of high and low LET radiation. The evidence relating to radon is, in contrast, of immediate practical importance: for millions of people are exposed to levels that are thought to cause material risks, which could be reduced by relatively simple means. The evidence described by Professor Lindell shows that radon can cause lung cancer and this has subsequently been confirmed by observations on many groups of men exposed to high levels in mines in Canada, China, the Czech Republic, England, France, Sweden, and the United States[13]. Radon can also cause carcinoma of the nasal sinuses when produced by the decay of radium in bone, as was described previously, and it may possibly cause a very slight risk of cancer in other sites, for it is dissolved in fat and, when inhaled, delivers doses to the liver, bone marrow, and kidney of one five hundredth to one hundredth of that to the lungs. No excess of cancer other than lung cancer could, however, be related to radon exposure in the pooled data for 11 groups of heavily exposed miners[14]. The possibility, suggested by Henshaw *et al*[15] on the basis of a geographical correlation, that radon may contribute to the production of cancer in children is not supported by a more detailed analysis, at least as far as childhood leukaemia is concerned[16]. If, however, radon does have any such effect it should be seen in the UK childhood cancer study, which, with the assistance of the NRPB, includes measurements of radon in the past and present residences of some 4500 children with cancer and some 9000 controls.

Radon in houses varies 100-fold from one part of the country to another, the highest levels overlapping those in mines in which a risk of lung cancer has been observed. Extrapolation of the risk in miners to lower levels is, however, fraught with difficulty; for the risk varies not only with total exposure and dose rate but also, in a way specific for lung cancer, with time since exposure and with the amount smoked. If this were not enough, there are the additional difficulties of extrapolating from male miners exposed in adult life, to members of the general public, who breathe less deeply, breathe air that is less contaminated with dust, were exposed in childhood, and include women. Temporary solutions have been proposed by the US National Research Council[17] and by Lubin *et al*[13] who conclude that the risk of lung cancer is related to the concentration of radon in air in a complex way, that depends on cumulative dose, dose rate, time since exposure, and age at risk. Lubin *et al*[13] suggest a formula for the excess risk, shown in Table 3. A parameter (γ) for duration allows for the greater risk at lower dose rates, but it would be preferable to derive a formula without this parameter, based on exposures only at levels below 10 WL, below which no further increase in risk has been observed to occur with decreasing dose rates[18]. As yet, however, insufficient data are available for this to be done.

Lubin *et al*[13] have used their formula to estimate the risk of lung cancer attributable to radon in houses in the United States. It led them to conclude that the risk was 10% in men and 12% in women. Smoking and radon did not appear, however, to multiply each other's effects, the two in combination causing somewhat less risk than multiplication would suggest. Separate estimates for smokers and non-smokers caused the coefficient β in Table 3 to be reduced to 0.0035 for smokers and increased to 0.0117 for non-smokers. The proportions attributable to radon in smokers remained about the same, but those for non-smokers became substantially greater (men 28%, women 31%). The formula has not yet been applied in Britain. As, however, the mean radon level is slightly less than half that in the US (20 against 46 Bq) the estimate is likely to be about 5% in both sexes.

With all the uncertainties relating to the use of this formula, we need to validate the results by direct observations on people with and without lung cancer, with known smoking habits and measured concentrations of radon in their homes. Such studies, however, also have great difficulties, including the need to measure concentrations in past places of residence, which may have been pulled down or altered, random errors in measurement, and differences in behaviour that affect the dose that individuals receive[19]. So far seven such studies have been reported. Four have led to estimates of risk not very different from those extrapolated from the experience of miners[20,23], while three have not suggested any risk at all[24–26]. Several others are in train and the best estimate of risk should eventually come from pooling the results.

Table 3. Relative risk of lung cancer resulting from exposure to radon (after Lubin *et al*[13]).

$$RR(w, \text{age, duration}) = 1 + \beta \times (w_{5-14} + \theta_2 w_{15-24} + \theta_3 w_{25+}) \times \Phi_{age} \times \gamma_{duration}$$

where

RR = risk of lung cancer relative to that without exposure

w = exposure in working level months (5–14, 15–24, and 25 or more years before age at risk)

β = 0.0039, θ_2 = 0.76, θ_3 = 0.31

Φ_{age} = 1.00 ages <55 y, 0.57 ages 55–64 y, 0.34 ages 65–74 y, 0.28 ages 75 and over

$\gamma_{duration}$ =		
1.00	for duration	<5 y
3.17	"	5–14 y
5.27	"	15–24 y
9.08	"	25–34 y
13.6	"	35 y and over

If we try to compare these risks with those produced by low LET radiation we encounter such difficulties in estimating the absorbed dose in the relevant tissue that ICRP[27] has recommended that risk estimates for radon should be based on the dose in air, in terms of WLM, instead of trying to express then in terms of sieverts or grays. Working in this way, Lubin *et al*[13] concluded that a lifetime dose, which in the US is estimated to be on average about 15 WLM (75 years at 0.2 WLM a year) causes about 10% of the lifetime risk of lung cancer. Consequently, as the lifetime risk for both sexes combined is about 6%, 1 WLM is estimated to cause a lifetime risk of 4×10^{-4}. The ICRP's[27] new lung model suggests that the absorbed dose in the lung from 1 WLM is approximately 5.4 mGy, and working with that and a radiation weighting factor of 20 we obtain an estimated risk of about 4×10^{-6} per mSV. With a tissue weighting factor of 0.12 and a halved risk for exposure at low dose rates, low LET radiation would, according to the International Commission for Radiological Protection[6] produce a corresponding risk of 6×10^{-6} per mSv. Alternatively, direct observation of the Japanese survivors would suggest a higher risk of 12.5×10^{-6} per mSv[11] and the difference would be greater if, as the author should prefer, the doses to different parts of the lung are weighted differently, with more weight given to the bronchi and less to the body of the lung. The appropriate absorbed dose would then be a little higher, say 7.4 mGy per WLM, leading to an estimated risk of about 3×10^{-6} per mSv for alpha radiation, now about a quarter of that directly estimated for low LET radiation and halved for low dose rates. The models used for projecting lifetime risks and the smoking habits of the different populations studied are, however, so different that the similarity of the estimates is, perhaps, more striking than their difference.

RADIOACTIVE IODINE

The last of the radionuclides for which we have worthwhile human evidence — namely, radioactive iodine — is used in medical therapy, diagnosis, and research and has been released in large amounts in nuclear accidents.

Use in medicine

Very large amounts of ^{131}I, of the order of 2000-10,000 MBq, have been given for the treatment of thyroid cancer. Iodine is concentrated in the thryoid and the dose to the thyroid has been of the order of 1000 Gy. Other organs have, however, received small fractions of the dose, particularly the bladder and the organs that excrete iodine (namely, salivary glands and stomach) which received doses of about 2 Gy, the small intestine which received a dose of about 1.3 Gy, and the bone marrow and breast which received doses of between 0.1 and 0.6 Gy. Smaller amounts of the order of 500 MBq have been given for the treatment of hyperthyroidism, and much smaller doses of about 2 MBq have been given to very large numbers of people for the diagnosis of thyroid disease.

Cohorts of patients receiving each of these levels of dose have been studied. Three cohorts treated for thyroid cancer have shown excesses of leukaemia, the sum of which is highly significant (9 cases against 1.99 expected, $p < 0.001$[28–30]). Data for cancers in other sites have been reported for only two of them[29,30], the sum of which is shown in Table 4. Statistically significant excesses were observed for cancers of the salivary gland and bladder, and a non-significant excess for cancer of the stomach, but no excess was observed for cancer of the breast.

The results with lower doses are confusing. In two large series of over 10,000 patients treated for hyperthyroidism, only a small and statistically non-significant excess of thyroid cancer was observed (21 cases against 14.8 expected[31,32]). Yet an excess was also observed in 34,000 Swedish patients given only diagnostic doses (50 cases against 39.4 expected). This was wholly concentrated in the period 5–9 years after exposure and seems likely to have been due to intensive medical surveillance and an increased rate of detection of indolent tumours and perhaps also to the underlying condition for which the test was given[33].

None of the cohorts treated for hyperthyroidism showed an excess of leukaemia, yet an excess was again observed in the Swedish patients given diagnostic doses, two orders of magnitude smaller (119 against 88.8 expected[33]). This, however, occurred equally with chronic lymphatic leukaemia and other types of leukaemia, although the former is generally thought not to be produced by ionising radiation, and it occurred only 15 and more years after treatment, when radiation-induced leukaemia would normally be expected to be uncommon. Again, therefore, it seems unlikely that the excess could be attributed to the diagnostic tests[33].

Comparison between the potential of radionuclides such as ^{131}I and external radiation to produce cancer of the thyroid has frequently been attempted and has

Table 4. Incidence of cancer following treatment of thyroid cancer with radioiodine (two cohorts).

Type of cancer	Standardised incidence rate	No of cases
Salivary glands	667*	3
Stomach	157	8
Bladder	240*	7
Breast (female)	102	15
Leukaemia	370*	7
Other	137	79

*$p < 0.05$.

always led to the conclusion that, dose for dose, ^{131}I was less effective. The most comprehensive review was carried out by Shore in 1992[34], who found a total excess of only 8.3 cases when 37.0 would have been expected based on the risk estimates for external exposure. According to UNSCEAR[1] a reduced risk may be attributed in part to the low dose rate, and partly, perhaps, to the non-uniformity of the dose throughout the gland[35].

Presence in fallout

Several studies have been reported of the effect of exposure to radioiodine in the fallout from nuclear explosions. The Marshall islanders were the first to experience such exposure from the Bravo thermonuclear test explosions in the Pacific in 1954. The thyroid doses were high, but the findings[36] are impossible to assess, because of the extent of thyroid surgery and the possible prophylactic effect of thyroid medication.

Kerber *et al*[37] did not have these difficulties in a survey of the incidence of thyroid cancer in 2500 children exposed to fallout from the Nevada tests in the mid 1950s. The excess relative risk per Gy was estimated to be 7, but the number of cases was small (8) and the estimate of dose subject to recall bias. The excess is, however, similar to that observed in cohorts of children irradiated externally for medical reasons, for whom Ron *et al*[38] obtained a pooled estimate of 7.7.

The most important findings should, however, be those related to the incidence of cancer in the neighbourhood of the Chernobyl explosions in October 1986. So far no notable excess of cancer has been observed other than of thyroid cancer in children, who are much more susceptible to the induction of thyroid cancer than adults. An excess began to be observed in 1990, a little sooner than had been seen after external medical irradiation. The early increase was initially thought to be an artefact due to the intensive programme for the detection of new cases, with nodules being discovered in the necks of children that would not normally have come to attention for several years, if, indeed, they would have ever. Now, however, the increase has been so great (Table 5) so many of the cases have been shown to be clinically malignant[41] and the initial rates so similar to those recorded in children elsewhere[42] that much of the increase must be real. It would indeed be surprising if it were not; for 300 children aged 0–7 years in the Gomel district of Belarus are estimated to have received thyroid doses of over 10 Gy and 32,000 to have received a mean dose of 1 Gy[43].

CONCLUSION

It is concluded, from this review, that the epidemiological evidence has shown that the risks of cancer from exposure to radionuclides emitting principally alpha and beta radiation have not been very different from those that would have been estimated from knowledge of the effect of low LET radiation using the classical radiation and dose rate weighting factors. In so far as the risks do differ, the evidence suggests that the weighting factor for alpha radiation may be too high or the dose rate factor too low, but the uncertainty surrounding the estimates of the absorbed doses are too great to allow much confidence to be placed in this conclusion. At least, however, the epidemiological evidence provides no reason to think that the opposite is true. As for the effect of beta radiation from ^{131}I in children, we shall have to wait a few more years until the effect of the Chernobyl explosion is better quantified.

Table 5. Thyroid cancer in children in Belarus and Ukraine, 1986–93[39,40].

Region	No of cases diagnosed in years:				1992–3/ 1986–9
	1986–7	1988–9	1990–1	1992–3	
*Belarus					
Gomel	3	4	58	70	20.0
3 neighbouring districts	2	5	18	56	16.0
3 further districts	1	3	12	19	9.5
*Ukraine					
6 neighbouring districts	3	6	25	61	13.6
Further districts	12	13	23	28	2.2

*Rate per 100,000 1986–89; Belarus 0.2, Ukraine 0.1.

REFERENCES

1. United Nations Scientific Committee on the Effects of Atomic Radiation. *Sources and Effects of Ionizing Radiation.* 1994 Report to the General Assembly with scientific annexes (New York: United Nations) (1994).
2. Stevens, W., Thomas, D. C., Lyon, J. L., Till, J. E., Kerber, R. A., Simon, S. L., Lloyd, R. D., Elghany, N. A. and Preston-Martin, S. *Leukaemia in Utah and Radioactive Fallout from the Nevada Test Site: a Case-control Study.* J. Am. Med. Assoc. **264**, 585–591 (1990).

3. Darby, S. C., Olsen, J. H., Doll, R., Thakrar, B., Brown, P. deN., Storm, H. H., Barlow, L., Langmark, F., Teppo, L. and Tulinius, H. *Trends in Childhood Leukaemia in the Nordic Countries in Relation to Fallout from Atmospheric Nuclear Weapons Testing*. Br. Med. J. **304**, 1005–1009 (1992).
4. Andersson, M. and Storm, H. H. *Cancer Incidence and Danish Thorotrast Exposed Patients*. J. Natl Cancer Inst. **84**, 1318–1325 (1992).
5. National Research Council. *Health Risks of Radon and other Internally Deposited Alpha-emitters. BEIR IV.* (Washington, DC: National Academy Press) (1988).
6. International Commission on Radiological Protection. *1990 Recommendations of the International Commission on Radiological Protection*. Publication 60. Ann. ICRP **21**(1–3) (Oxford: Pergamon) (1990).
7. Trott, K.-R. *Lessons from Thorotrast*. (to be published) (1996).
8. Spiers, F. W. *et al. Leukaemia Incidence in the US Dial Painters*. Health Phys. **44**(Suppl. 1), 65–72 (1983).
9. Polednak, A. P., Stehney, A. F. and Rowland, R. E. *Mortality among Women First Employed before 1930 in the US Radium Dial Painting Industry*. Am. J. Epidemiol. **107**, 179–195 (1978).
10. Spiess, H. and Mays, C. W. *Protraction Effect on Bone Sarcoma Induction of Radium 224 in Children and Adults*. In: Radionuclide Carcinogenesis. Eds. C. L. Sanders *et al* CONF-720505 (1973).
11. Spiess, H., Mays, C. W. and Chmelevsky, D. *Malignancies in Patients Injected with ^{224}Ra*. In: Risks from Radium and Thorotrast. Eds. D. M. Taylor, *et al* pp. 7–12 (London: British Institute of Radiology) (1989).
12. Chmelevsky, D. *et al. The Reverse Protraction Factor in the Induction of Bone Sarcomas in Radium-225 Patients*. Radiat. Res. **124**, 569–579 (1990).
13. Lubin, J. H. *et al. Lung Cancer in Radon-Exposed Miners and Estimation of Risk from Indoor Exposure*. J. Natl Cancer Inst. **87**, 817–827 (1995).
14. Darby, S. C. *et al. Radon and Cancers other than Lung Cancer in Underground Miners: a Collaborative Analysis of 11 Studies*. J. Natl. Cancer Inst. **87**, 378–383 (1995).
15. Henshaw, D. L., Eatough, J. P. and Richardson, R. B. *Radon as a Causative Factor in Induction of Myeloid Leukaemia and other Cancers*. Lancet **335**, 1008–1012 (1990).
16. Richardson, S., Monfort, C., Green, M., Draper, G. and Muirhead, C. *Spatial Variation of Natural Radiation and Childhood Leukaemia in Great Britain*. Stat. Med. **14**, 2487–2501 (1995).
17. National Research Council. *Comparative Dosimetry of Radon in Mines and Homes*. (Washington, DC: National Academy Press) (1991).
18. Tomasek, L., Darby, S. C., Fearn, T., Swerdlow, A. J., Placek, V. and Kunze, E. *Patterns of Lung Cancer Mortality among Uranium Miners in West Bohemia with Varying Rates of Exposure to Radon and its Progeny*. Radiat. Res. **137**, 251–261 (1994).
19. Lubin, J. H., Boice, J. D. and Samet, J. M. *Errors in Exposure Assessment, Statistical Power, and the Interpretation of Residential Radon Studies*. Radiat. Res. (in press) (1995).
20. Schoenberg, J. B., Klotz, J. B., Wilcox, H. B., Nicholls, G. P., Gil-Del-Real, M. T., Stemhagen, A. and Mason, T. J. *Case-control Study of Residential Radon and Lung Cancer among New Jersey Women*. Cancer Res. **50**, 6520–6524 (1990).
21. Ruosteenoja, E. *Indoor Radon and Risk of Lung Cancer: an Epidemiological Study in Finland*. Doctoral dissertation, Department of Public Health, University of Tampere (Finnish Government Printing Office, Helsinki) (1991).
22. Pershagen, G., Liang, Z.-H., Hrubec, Z., Svensson, C. and Boice, J. D. *Residential Radon Exposure and Lung Cancer in Swedish Women*. Health Phys. **63**, 179–186 (1992).
23. Pershagen, G. *et al. Residential Radon Exposure and Lung Cancer in Sweden*. New Engl. J. Med. **330**, 159–164 (1994).
24. Blot, W. J., Xu, Z., Boice, J. D., Zhao, D., Stone, B. J., Sun, J., Jing, L. and Fraumeni, J. F. *Indoor Radon and Lung Cancer in China*. J. Natl Cancer Inst. **82**, 1025–1030 (1990).
25. Alavanja, M. C. R., Brownson, R. C., Lubin, J. H., Brown, C., Berger, C. and Boice, J. D. *Residential Radon Exposure and Lung Cancer among Non-smoking Women*. J. Natl Cancer Inst. **86**, 1829–1837 (1994).
26. Létourneau, E. G., Krewski, D., Choi, N. W., Goddard, M. J., McGregor, R. G., Zielinski, J. M. and Du, J. *Case-control Study of Residential Radon and Lung Cancer in Winnipeg, Manitoba, Canada*. Am. J. Epidemiol. **140**, 310–322 (1994).
27. International Commission on Radiological Protection. *Human Respiratory Tract Model, for Radiological Protection*. ICRP Publication (Oxford: Pergamon) (1994).
28. Brincker, H., Hansen, H. S. and Andersen, A. P. *Induction of Leukaemia by ^{131}I Treatment of Thyroid Carcinoma*. Br. J. Cancer **28**, 232–237 (1973).
29. Edmonds, C. J. and Smith, T. *The Long-term Hazard of the Treatment of Thryoid Cancers with Radioiodine*. Br. J. Radiol. **59**, 45–51 (1986).
30. Hall, P., Holm, L.-E., Lundell, G., Bjelkengren, G., Larsson, L.-G., Lindberg, S., Tennvall, J., Wicklund, H. and Boice, J. D. *Cancer Risks in Thyroid Cancer Patients*. Br. J. Cancer **64**, 159–163 (1991).
31. Holm, L. E. *et al. Cancer Risk after Iodine-131 Therapy for Hyperthyroidism*. J. Natl Cancer Inst. **83**, 1072–1077 (1991).
32. Hoffman, D. A. *Late Effects of I-131 Therapy in the United States*. In: Radiation Carcinogenesis Epidemiology and Biological Significance. Eds. J. D. Boice and J. F. Fraumeni. pp. 273–280 (New York: Raven Press) (1984).

33. Holm, L. E. *et al. Cancer Risk in Population Examined with Diagnostic Doses of* ^{131}I. J. Natl Cancer Inst. **81**, 302–306 (1989).
34. Shore, R. E. *Issues and Epidemiological Evidence Regarding Radation-induced Thyroid Cancer*. Radiat. Res. **131**, 98–111 (1992).
35. Sinclair, W. K. *et al. A Quantitative Autoradiographic Study of Radioactive Distribution and Dosage in Human Thyroid Glands*. Br. J. Radiol. **29**, 36–41 (1956).
36. Robbins, J. and Adams, W. *Radiation Effects in the Marshall Islands*. In: Radiation and the Thyroid. Ed. S. Nagasaki, pp. 11–24 (Tokyo: Excerpta Medica) (1989).
37. Kerber, R. A. *et al. A Cohort Study of Thyroid Disease in Relation to Fallout from Nuclear Weapons Testing*. J. Am. Med. Assoc. **270**, 2076–2082 (1993).
38. Ron, E., Lubin, J. H., Shore, B. E., Mabuchi, K., Modan, B., Pottern, C. M., Schneider, A.-B., Tucker, M. A. and Boice, J. D. *Thyroid Cancer after Exposure to External Radiation: a Pooled Analysis of Seven Studies*. Radiat. Res. **141**, 259–277 (1995).
39. Demidchik, E. P. *et al. Thyroid Cancer in Children after the Chernobyl Accident: Clinical and Epidemiological Evaluation of 251 Cases in the Republic of Belarus*. In: Symposium on Chernobyl: Update and Future. Ed. S. Nagasaki, pp. 21–30. (Amsterdam: Elsevier) (1994).
40. Tronko, N. *et al. Thyroid Gland in Children after the Chernobyl Accident (Yesterday and Today)*. In: Symposium on Chernobyl: Update and Future. Ed. S. Nagasaki, pp. 31–46 (Amsterdam: Elsevier) (1994).
41. Fermanchuk, A. W. *et al. Pathomorphological Findings in Thyroid Cancers of Children from the Republic of Belarus: a Study of 86 Cases Occurring between 1986 (post Chernobyl) and 1991*. Histopathology **21**, 401–408 (1992).
42. International Agency for Research on Cancer. *International Incidence of Childhood Cancer*. IARC Scientific Publication No 87. Eds D. M. Parkin, C. A. Stiller, G. J. Draper, C. A. Bieber, B. Terracini and J. L. Young (Lyon: International Agency for Research on Cancer) (1988).
43. Barkhudaran, R. M. *et al. Characterisation of Radiation Levels of the Population in the Controlled Areas within the First Four Years after the Chernobyl NPP Accident*. (Moscow: Institute of Physics) (1994).

ATTACHMENT 5

Background Information

on

Radioactive Material and Radiation

U.S. Nuclear Regulatory Commission

Background Information
on
Radioactive Material and Radiation

The Nuclear Regulatory Commission (NRC) developed this pamphlet to provide information about radiation and the health risks associated with radiation and radioactive material. This pamphlet specifically addresses the radioactive contamination that has been found in the vicinity of Cambridge and Byesville, Ohio. Based on the type of contamination and the composition of the materials that contain it, NRC believes that the contamination was caused when slag, which was produced in processing metals at a plant near Cambridge, was transported offsite and used for construction purposes. NRC believes that additional assessment of this contamination is necessary to determine its extent, evaluate long-term risks that it may pose to nearby residents, and assess the need to reduce contamination levels to protect the public.

Why should I be Concerned?

The contamination present near Cambridge and Byesville may present a potential long-term hazard to exposed individuals. The radioactive materials that comprise the contamination give off radiation. People exposed directly to the radiation or that ingest or inhale the contamination may be at greater risk as a result of the radiation exposure. NRC has developed guidelines on what concentrations of radioactive materials in soils and other materials would generally be acceptable in public areas. Based on preliminary assessments, NRC has determined that contamination levels at several sites exceed these guidelines. The levels of contamination detected by NRC are generally quite low. Nevertheless, there is concern that even low levels of radiation may pose health hazards to those who might be exposed over long periods of time.

Who is NRC?

The NRC regulates the civilian uses of certain radioactive materials used by or generated in nuclear power reactors (source, special nuclear, and byproduct materials) in the United States. NRC's mission is to protect the public health and safety, the environment, and the common defense and security. This mission is accomplished through: licensing nuclear facilities and the possession, use and disposal of nuclear materials; the development and implementation of guidance and requirements governing licensed activities; and inspection and enforcement activities to ensure compliance with these requirements. States may also sign agreements with the NRC to regulate most types of radioactive material within their borders. The State of Ohio is currently preparing to establish such an agreement with the NRC.

There are other radioactive materials that NRC does not regulate. Radioactive materials that occur naturally, other than uranium and thorium, are not regulated by NRC. In lieu of Federal regulations, States have the responsibility to regulate naturally occurring radioactive material. In addition, NRC does not generally regulate defense nuclear activities conducted by the U.S. Department of Energy. This is because the U.S. Congress did not provide NRC with the legal authority to

regulate these materials. Various other Federal agencies, such as the Environmental Protection Agency, Department of Transportation, and Health and Human Services, and State agencies also have a role in the regulation of radioactive material.

What is Radiation?

We have always been subjected to natural radiation from outer space, from naturally occurring radioactive materials in soils, in the food and water we consume, and in the buildings where we live and work. The term "radiation" as it relates to radioactive material regulated by NRC means the energy given off by the material as it decays. Ionizing radiation produces charged particles, or ions, in the material in which it encounters. The process of ionization can cause disease and injury to plants and animals.

There are five major types of ionizing radiation:

- Alpha radiation - positively charged particles that are emitted from naturally occurring and man-made radioactive material. Uranium, thorium and radium emit alpha radiation and so they are called "alpha emitters." Most alpha particles can be stopped by a single sheet of paper or skin. Consequently, the principle hazard from alpha emitters to humans is caused when the material is ingested or inhaled. The limited penetration of the alpha particle means that the energy of the particle is deposited within the tissue (e.g., lining of the lungs) nearest the radioactive material once inhaled or ingested.

- Beta radiation - negatively charged particles that are typically more penetrating but have less energy than alpha particles. Beta particles can penetrate human skin or sheets of paper, but can usually be stopped by thin layers of plastic, aluminum, or other materials. Carbon-14 (^{14}C) and Hydrogen-3 (^{3}H or tritium) are two common "beta emitters." Although they can penetrate human skin, beta particles are similar to alpha particles in that the predominant hazard to humans comes from ingesting or inhaling the radioactive materials that emit beta radiation.

- Gamma radiation - the most penetrating type of radiation, gamma rays are very penetrating and can be highly energetic. They can pass through the human body and common construction materials. Thick and dense layers of concrete, steel, or lead are used to stop gamma radiation from penetrating to areas where humans can be exposed. Technetium-99m (^{99m}Tc) is an example of a "gamma emitter" that is widely used in medical diagnosis. Gamma emitters can pose both external and internal radiation hazards to humans.

- Neutron radiation - neutrally charged particles, neutrons can also be very penetrating. Neutron radiation can be created in nuclear reactors and linear accelerators. There are no naturally occurring neutron emitters.

- X-rays - the most familiar type of radiation, x-rays are very similar to gamma rays although they are produced in a different part of an atom. Most people have had an x-ray taken by a physician as part of their normal health care.

The penetrating power of these various types of ionizing radiation is illustrated in Figure 1.

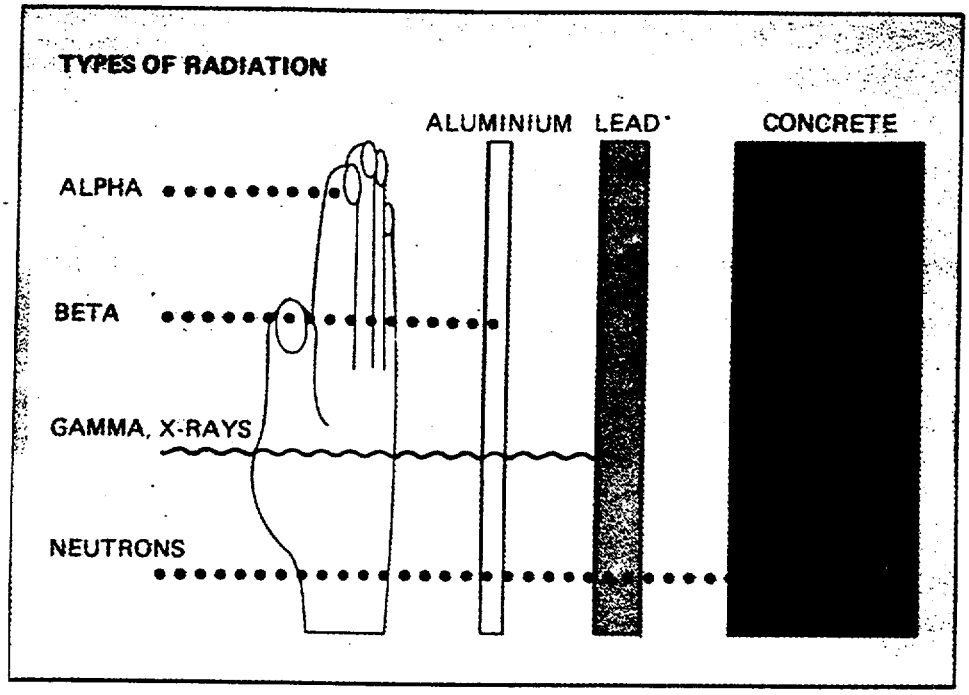


Figure 1. Penetrating power of the various types of radiation.

How is Radiation Measured?

Whether it emits alpha or beta particles, gamma or X-rays or neutrons, the quantity of radioactive material is typically expressed in terms of its "radioactivity" or simply its "activity" and is measured in curies. One curie equals 37 billion atomic disintegrations per second. *Activity* is used to describe a material, just as one would discuss the length or weight of a material. For example, one would say "the activity of the uranium in the container is 2 curies." Generally, the larger the activity of the material, the greater the potential health hazard associated with that material if it is not properly controlled. At nuclear power reactors, the activity of radioactive material may be described in terms of hundreds to millions of curies, whereas the units typically used to describe activity in the environment are often microcuries (μCi) or picocuries (pCi). A microcurie is one one-millionth (1/1,000,000) of a curie and a picocurie is one one-trillionth (1/1,000,000,000,000) of a curie.

The activity of a radioactive material decreases or *decays* at a constant rate. The time taken for the activity of a radioactive material to decrease by half is called the *radioactive half-life*. After one half-life, the remaining activity would be one half (1/2) of the original activity. After two half-lives, the remaining activity would be one fourth (1/4), after three one eighth, and so on. For example, if a radioactive material has a half-life of 10 years, the amount of material remaining

after 10 years would be 1/2 of that originally present. After 100 years (10 half-lives), the remaining activity would be 1/1024 of the amount that was originally present. Some radioactive materials have extremely short half-lives measured in terms of minutes or hours. Others, such as natural uranium, have half-lives measured in terms of millions to billions of years. Natural thorium has a half-life of 14 billion years. Natural uranium has a half-life of 4.5 billion years.

Some radioactive materials decay to form other radioactive materials. These so-called decay products, in turn, decay to form still other radioactive materials. Each material formed through decay has a unique set of radiological properties, such as half-life and energy given off through decay. In the case of the contamination found near Cambridge and Byesville, OH, the radioactive materials present consist of three separate decay "chains" or "series": uranium, thorium, and actinium decay chains. These decay chains are summarized in Figure 2.

Uranium	**Thorium**	Actinium
Uranium-238	**Thorium-232**	Uranium-235
↓	↓	↓
Uranium-234	**Radium-228**	Protactinium-231
↓	↓	↓
Thorium-230	**Thorium-228**	Actinium-227
↓	↓	↓
Radium-226	**Radium-224**	Radium-233
↓	↓	↓
Radon-222	**Lead** (Stable)	Bismuth-207
↓		↓
Lead-210		Lead (Stable)
↓		
Lead (Stable)		

Figure 2. Decay chains present in Offsite Contamination at Cambridge and Byesville (radioactive materials with short half-lives or minimal analytical significance omitted)

Some of the radioactive materials in these chains emit gamma rays when they decay. The intensity of gamma radiation in air or *exposure rate* is measured in Roentgens (R) or microRoentgens (μR) per unit time, usually an hour, as in R/hr or μR/hr. In the environment, exposure rates are typically measured in terms of μR/hr. For example, in many parts of the United States the exposure rate from natural sources of radiation is between 5 and 15 μR/hr. This ambient level is referred to as the background exposure rate. In the vicinity of Cambridge and Byesville, the background exposure rate averages about 10 μR/hr and ranges about 6 to 14 μR/hr.

Many commercially available radiation detectors measure radiation fields in terms of μR/hr or counts per minute (cpm). "CPM" refers to the number of ionizing particles striking the detector surface in a minute. A fraction of these particles are recorded by the detector as counts. The number of counts per minute can then be related to exposure rate or radiation dose for a known radioactive material using a standard set of assumptions.

Radiation *dose* or the measurement of the body's exposure to ionizing radiation is measured in units of rem. In the environment, doses are often measured in terms of millirem. A millirem is one one-thousandth (1/1,000) of a rem; a microrem is one-millionth of a rem (1/1,000,000). The *dose rate* is expressed in terms of dose per unit time, again usually an hour, as millirem/hr. For external radiation, exposure rates are often equated to dose rates using the conversion of 1 μR/hr $\approx$ 1 microrem/hr. Doses from internal exposure from radioactive material that has been ingested or inhaled are more difficult to determine. Computer models that account for the distribution and excretion of the radioactive material within the body are used for estimating doses and dose rates from internal radioactive contamination.

What is background radiation?

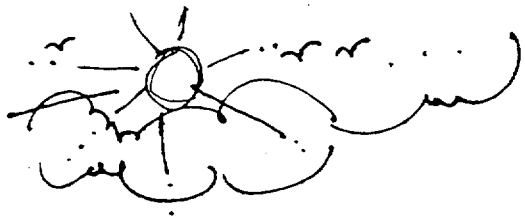
"Background radiation" is the radiation that is emitted from all things in and on the Earth and in space. Almost everything, including people, contain some radioactive material. Naturally occurring radioactive materials are found in the earth, in the materials used to build our homes, and in the food and water we ingest. Even the air we breathe contains some radioactive gases.

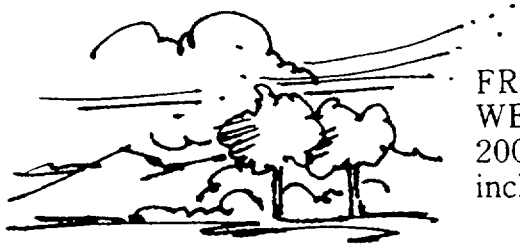
It is estimated that on average every individual in the U.S. receives slightly more than 300 millirem per year from their exposure to background radiation. On the average, Americans receive about 30 millirem per year from cosmic radiation from space, 200 millirem per year from radon in the air we breathe, 40 millirem per year from food and drink, and 30 millirem per year from soils and building materials.

Of course, these doses can vary greatly, as the various factors that contribute to background radiation are not constant from location to location. Our lifestyles and daily activities vary these amounts to some extent. For example, a flight on a commercial airliner increases your dose from cosmic gamma rays about 4 to 5 millirem for each cross-country flight. If you live in a brick home instead of one made of wood, you may add up to 10 millirem per year to your annual dose due to naturally occurring thorium, uranium, and radium found in the clays of which bricks are made. Figure 3 illustrates various sources and amounts of natural background radiation.

Examples of natural radiation exposure

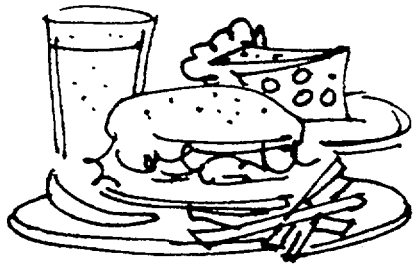
FROM THE SKY—About 30 millirem per year from cosmic radiation.

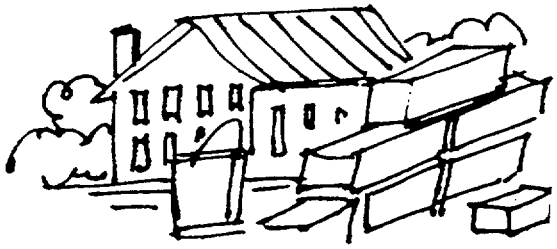




FROM THE AIR THAT WE BREATHE—About 200 millirem per year, including radon.

FROM OUR FOOD AND DRINK—About 40 millirem per year from natural radioactive materials such as potassium-40.





FROM SOILS AND BUILDING MATERIALS—About 30 millirem per year from natural radionuclides such as uranium.

Naturally occurring sources of radiation are all around us. This chart shows the average annual radiation dose from natural background sources.

Figure 3. Examples of Natural Radiation Exposure

In addition to background radiation, radioactive materials are found in consumer products. For example, most domestic smoke detectors contain the radioactive material americium. In the practice of nuclear medicine, radioactive materials are administered to patients for the diagnosis or treatment of illnesses such as cancer or Graves disease. Laboratories and universities use radioactive materials in research, including the marking and detection of molecules in genetic research, the study of human and animal organ systems, and in the development of new drugs.

What are the effects of radiation exposure?

When radiation passes into and through living tissue, it damages some cells in the body. Some cells may not survive the damage and die while other cells will survive the damage and reproduce normally. Other damaged cells may survive, but in a modified form, which may later result in cancer. Other health effects from low doses of radiation may include birth defects and inherited diseases. Very large doses of radiation over short periods of time may cause organ damage and, if high enough, death. Doses associated with natural background exposures are thousands of times lower than the high doses that are so destructive.

At low doses, the principal concern is the possible occurrence of cancer years after the exposure to the radiation. Other effects such as birth defects and inherited diseases are less likely. For such low doses, the likelihood of producing cancer has not been directly established because it is impossible to distinguish cancers produced by such low levels of radiation from cancers produced by other sources, such as harmful chemicals in the environment. Therefore, in estimating the consequences of any exposure to radiation, it is assumed that the chance of developing cancer is linearly proportional to dose and that there is no threshold below which there is no chance of cancer. This chance, or risk, is expressed in terms of *probability* of an adverse health effect because a given dose of radiation dose not produce a cancer in all cases. The NRC uses the linear assumption and the philosophy that radiation exposure should be kept as low as reasonably achievable (ALARA) in regulating the use of nuclear materials.

How can I protect myself from radiation?

There are three important factors to keep in mind to protect yourself from sources of ionizing radiation. These factors are:

- Time - The longer an individual is near a source of radiation, the greater the potential dose will be. Decreasing the amount of time spent near a source of radiation can significantly reduce the potential dose.

- Distance - Radiation exposure rates decrease proportionally with the distance from the source of the radiation. For example, if you move twice as far away from a source of radiation, your exposure will be one quarter of the dose received at the original distance. Increasing the distance from a source of radiation can significantly decrease the potential dose.

- Shielding - Any material placed between you and a source of radiation will reduce the exposure you will receive under most situations. Different types of radiation are stopped (or attenuated) more effectively by

different materials. Placing any material between yourself and a source of radiation can reduce the potential dose.

What risks are associated with the offsite contamination?

The amount of risk associated with the contamination varies based on several factors, including the type and concentration of radioactive materials present, the size of the contaminated area, accessibility of the contamination, chemical form of the contamination, and proximity to living areas. Estimates of risk or radiological dose could be developed for any individual based on information on these factors and additional assessments of the radiological contamination. However, these values would remain estimates because actual risks vary from person to person based on human sensitivities and a variety of other factors that are not completely understood.

NRC has only conducted a limited assessment of radiological contamination that may exist offsite in the Cambridge and Byesville areas. This assessment indicates a wide variety of concentrations exist of the radioactive materials listed in Figure 2. The principal radioactive materials found offsite and their characteristics are listed in the table below.

Radioactive Material	Decay Chain	Half-life (Years)	Primary Hazards
Uranium-238/ Uranium-234	Uranium	4,500,000,000	Ingestion; inhalation; prolonged contact
Thorium-230	Uranium	77,000	Ingestion; inhalation
Radium-226	Uranium	1600	External; ingestion; inhalation
Radon-222	Uranium	0.01	Inhalation
Thorium-232/ Thorium-228	Thorium	14,000,000,000	External; ingestion; inhalation
Protactinium-231	Actinium	33,000	Inhalation; ingestion
Actinium-227	Actinium	22	Inhalation; ingestion

The concentrations of these radioactive materials are reported in NRC's inspection report in concentrations of picoCuries per gram (pCi/g) in the samples collected. Owners of properties that were sampled should check the concentrations for each type of radioactive material listed for the location. In many cases, NRC only collected and analyzed a single sample because measurements of gamma-radiation performed by

NRC staff and contractors on site did not indicate the presence of radiological contamination. However, more detailed analysis indicated some sites had elevated levels of contamination that would not be readily detected by field surveys. Consequently, additional sampling and analysis is necessary to further assess the extent and significance of radiological contamination at offsite properties.

As a guide to assessing and considering potential removal of radiological contamination, NRC staff has developed the criteria listed below. These criteria describe the concentrations of radioactive materials in soils and other materials resulting from use or processing of radioactive materials that NRC has determined to be generally be acceptable in public areas. Concentrations *above* these criteria do not indicate immediate hazards to the public. For example, concentrations ten times greater than some of the criteria may ultimately be found acceptable. However, detailed assessment of such contamination would be necessary before a decision can be made on a case-by-case basis to ensure protection of the public over long periods of exposure. Consequently, these criteria should be applied to determine whether more detailed assessment of the contamination is necessary, including consideration of removal or reduction of the contamination.

Radioactive Material	Criterion (pCi/g)
Uranium-238/ Uranium-234	10 (total uranium)
Thorium-230	3
Radium-226	5
Radon-222	4 pCi/l (in air)
Thorium-232/ Thorium-228	10 (total thorium)
Protactinium-231	0.3
Actinium-227	0.4

Using standard models and assumptions of how individuals could be exposed to the contamination, NRC staff has estimated potential doses from the offsite contamination. These models, for example, assume that an individual spends 55% of the year indoors on site, 21% of the year outside (5 hours a day), and 24% of the time away from the site. They also assume that the exposed individual grows and ingests up to 50% of his or her vegetables on site, consumes meat and milk produced on site, and consumes aquatic food (fish and shellfish) from a pond near the site. The models also assume that all of the individual's drinking water is extracted from a well onsite.

For most of the radionuclides, NRC's guidelines correspond to doses less than several tens of millirem per year, assuming that individuals are extensively exposed to the contamination. Less extensive exposure would result in correspondingly smaller potential doses. Higher doses are associated with existing criteria for radium-226 and radon-222, which are based on standards and guidance developed by the U.S. Environmental Protection Agency (EPA). NRC and EPA are both currently developing new regulations for residual contamination. Once these regulations have been issued, NRC anticipates that they will replace existing criteria with standards that ensure a more consistent level of protection for the public and the environment.

Actual doses will vary considerably based on the factors described above. For example, if the contamination is buried beneath a paved driveway or beneath a driveway covered with several inches of uncontaminated material as is commonly the case in the Cambridge area, doses under current conditions may approach zero because: (1) humans are not directly exposed to the contamination; (2) the material is not leaching into the groundwater; and (3) contaminated soil is not being eaten or used for growing crops. However, the contamination may still pose a long-term concern, for example, if the driveway were removed and the contamination exhumed at some point in the future. Some of the radioactive materials decay to form the radioactive gas radon, which may accumulate within residences and other structures and result in significant doses to individuals. The potential for such exposures needs to be considered in evaluating contamination on each property.

Comments or Questions?

If you have any questions or comments, please contact James Kennedy of the NRC staff at 1-800-368-5642 or via e-mail at jekl@nrc.gov.

# # #

ATTACHMENT 6

code of federal regulations

Energy

10

PARTS 1 TO 50

Revised as of January 1, 1998

the order shall include a schedule for discovery and subsequent oral argument with respect to the admitted contentions.

(c) If no party to the proceeding requests oral argument, or if all untimely requests for oral argument are denied, the presiding officer shall conduct the proceeding in accordance with subpart G of 10 CFR part 2.

§ 2.1111 Discovery.

Discovery shall begin and end at such times as the presiding officer shall order. It is expected that all discovery shall be completed within 90 days. The presiding officer may extend the time for discovery upon good cause shown based on exceptional circumstances and after providing the other parties an opportunity to respond to the request.

§ 2.1113 Oral argument.

(a) Fifteen (15) days prior to the date set for oral argument, each party, including the NRC staff, shall submit to the presiding officer a detailed written summary of all the facts, data, and arguments which are known to the party at such time and on which the party proposes to rely at the oral argument either to support or to refute the existence of a genuine and substantial dispute of fact. Each party shall also submit all supporting facts and data in the form of sworn written testimony or other sworn written submission. Each party's written summary and supporting information shall be simultaneously served on all other parties to the proceeding.

(b) Only facts and data in the form of sworn written testimony or other sworn written submission may be relied on by the parties during oral argument, and the presiding officer shall consider those facts and data only if they are submitted in that form.

§ 2.1115 Designation of issues for adjudicatory hearing.

(a) After due consideration of the oral presentation and the written facts and data submitted by the parties and relied on at the oral argument, the presiding officer shall promptly by written order:

(1) Designate any disputed issues of fact, together with any remaining issues of law, for resolution in an adjudicatory hearing; and

(2) Dispose of any issues of law or fact not designated for resolution in an adjudicatory hearing.

With regard to each issue designated for resolution in an adjudicatory hearing, the presiding officer shall identify the specific facts that are in genuine and substantial dispute, the reason why the decision of the Commission is likely to depend on the resolution of that dispute, and the reason why an adjudicatory hearing is likely to resolve the dispute. With regard to issues not designated for resolution in an adjudicatory hearing, the presiding officer shall include a brief statement of the reasons for the disposition. If the presiding officer finds that there are no disputed issues of fact or law requiring resolution in an adjudicatory hearing, the presiding officer shall also dismiss the proceeding.

(b) No issue of law or fact shall be designated for resolution in an adjudicatory hearing unless the presiding officer determines that:

(1) There is a genuine and substantial dispute of fact which can only be resolved with sufficient accuracy by the introduction of evidence in an adjudicatory hearing; and

(2) The decision of the Commission is likely to depend in whole or in part on the resolution of that dispute.

(c) In making a determination under paragraph (b) of this section, the presiding officer shall not consider:

(1) Any issue relating to the design, construction, or operation of any civilian nuclear power reactor already licensed to operate at the site, or any civilian nuclear power reactor for which a construction permit has been granted at the site, unless the presiding officer determines that any such issue substantially affects the design, construction, or operation of the facility or activity for which a license application, authorization, or amendment to expand the spent nuclear fuel storage capacity is being considered; or

(2) Any siting or design issue fully considered and decided by the Commission in connection with the issuance of a construction permit or operating license for a civilian nuclear power reactor at that site, unless (i) such issue results from any revision of siting or design criteria by the Commission following such decision; and (ii) the presiding officer determines that such issue substantially affects the design, construction, or operation of the facility or activity for which a license application, authorization, or amendment to expand the spent nuclear fuel storage capacity is being considered.

(d) The provisions of paragraph (c) of this section shall apply only with respect to licenses, authorizations, or amendments to licenses or authorizations applied for under the Atomic Energy Act of 1954, as amended, before December 31, 2005.

(e) Unless the presiding officer disposes of all issues and dismisses the proceeding, appeals from the presiding officer's order disposing of issues and designating one or more issues for resolution in an adjudicatory hearing are interlocutory and must await the end of the proceeding.

[50 FR 41671, Oct. 15, 1985; 50 FR 45398, Oct. 31, 1985]

§ 2.1117 Applicability of other sections.

In proceedings subject to this subpart, the provisions of subparts A and G of 10 CFR part 2 are also applicable, except where inconsistent with the provisions of this subpart.

Subpart L—Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings

SOURCE: 54 FR 8276, Feb. 28, 1989, unless otherwise noted.

§ 2.1201 Scope of subpart.

(a) The general rules of this subpart govern procedure in any adjudication initiated by a request for a hearing in a proceeding for—

(1) The grant, transfer, renewal, or licensee-initiated amendment of a materials license subject to parts 30, 32 through 35, 39, 40, or 70 of this chapter; or

(2) The grant, renewal, or licensee-initiated amendment of an operator or

senior operator license subject to part 55 of this chapter.

(3) The amendment of a Part 50 license following permanent removal of fuel from the Part 50 facility to an authorized facility for licensees that have previously made declarations related to permanent cessation of operations and permanent removal of fuel from the reactor in accordance with § 50.82(a)(1). Subpart L hearings for the license termination plan amendment, if conducted, must be completed before license termination.

(b) Any adjudication regarding, (1) a materials license subject to parts 30, 32 through 35, 39, 40, or 70, or an operator or senior operator license subject to part 55 that is initiated by a notice of hearing issued under § 2.104, or (2) a notice of proposed action under § 2.105, or a request for hearing under subpart B of 10 CFR part 2 on an order or a civil penalty, is to be conducted in accordance with the procedures set forth in subpart G of 10 CFR part 2.

[57 FR 4153, Feb. 4, 1992, as amended at 61 FR 39297, July 29, 1996]

§ 2.1203 Docket; filing; service.

(a) The Secretary shall maintain a docket for each adjudication subject to this subpart, commencing with the filing of a request for a hearing. All papers, including any request for a hearing, petition for leave to intervene, correspondence, exhibits, decisions, and orders, submitted or issued in the proceeding; the hearing file compiled in accordance with § 2.1231; and the transcripts of any oral presentations or oral questioning made in accordance with § 2.1235 or in connection with any appeal under this subpart must be filed with the Office of the Secretary and must be included in the docket. The public availability of official records relating to the proceeding is governed by § 2.790.

(b) Documents are filed with the Office of the Secretary in adjudications subject to this subpart either—

(1)(i) By delivery to the Rulemakings and Adjudications Staff of the Office of the Secretary at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(ii) By mail, telegram or facsimile addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

(2) Filing by mail, telegram or facsimile is complete as of the time of deposit in the mail, with the telegraph company, or upon facsimile transmission. Filing by other means is complete as of the time of delivery to the Rulemakings and Adjudications Staff of the Office of the Secretary.

(c) Each document submitted for filing in an adjudication subject to this part, other than an exhibit, must be legibly typed, must bear the docket number and the title of the proceeding, and, if it is the first document filed by that participant, must designate the name and address of a person upon whom service can be made. The document also must be signed in accordance with § 2.708(c). A document, other than correspondence, must be filed in an original and two conforming copies. Documents filed by telegram are governed by § 2.708(f). A document that fails to conform to these requirements may be refused acceptance for filing and may be returned with an indication of the reason for nonacceptance. Any document tendered but not accepted for filing may not be entered in the docket.

(d) Computation of time and extension and reduction of time limits is done in accordance with §§ 2.710–2.711.

(e) A request for a hearing or petition for leave to intervene must be served in accordance with § 2.712 and § 2.1205(f) and (R). All other documents issued by the presiding officer or the Commission or offered for filing are served in accordance with § 2.712.

[54 FR 8276, Feb. 28, 1989, as amended at 61 FR 39297, July 29, 1996; 62 FR 27495, May 20, 1997]

§ 2.1205 Request for a hearing; petition for leave to intervene.

(a) Any person whose interest may be affected by a proceeding for the grant, transfer, renewal, or licensee-initiated amendment of a license subject to this subpart may file a request for a hearing.

(b) An applicant for a license, a license amendment, a license transfer, or a license renewal who is issued a notice of proposed denial or a notice of denial

and who desires a hearing shall file the request for the hearing within the time specified in § 2.103 in all cases. An applicant may include in the request for hearing a request that the presiding officer recommend to the Commission that procedures other than those authorized under this subpart be used in the proceeding, provided that the applicant identifies the special factual circumstances or issues which support the use of other procedures.

(c) For amendments of Part 50 licenses under § 2.1201(a)(3), a notice of receipt of the application, with reference to the opportunity for a hearing under the procedures set forth in this subpart, must be published in the FEDERAL REGISTER at least 30 days prior to issuance of the requested amendment by the Commission.

(d) A person, other than an applicant, shall file a request for a hearing within—

(1) Thirty days of the agency's publication in the FEDERAL REGISTER of a notice referring or relating to an application or the licensing action requested by an application, which must include a reference to the opportunity for a hearing under the procedures set forth in this subpart. With respect to an amendment described in § 2.1201(a)(3), other than the one to terminate the license, the Commission, prior to issuance of the requested amendment, will follow the procedures in § 50.91 and § 50.92(c) to the extent necessary to make a determination on whether the amendment involves a significant hazards consideration. If the Commission finds there are significant hazards considerations involved in the requested amendment, the amendment will not be issued until any hearings under this paragraph are completed.

(2) If a FEDERAL REGISTER notice is not published in accordance with paragraph (d)(1), the earliest of—

(i) Thirty days after the requester receives actual notice of a pending application, or

(ii) Thirty days after the requester receives actual notice of an agency action granting an application in whole or in part, or

(iii) One hundred and eighty days after agency action granting an application in whole or in part.

clear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

(2) Filing by mail, telegram or facsimile is complete as of the time of deposit in the mail, with the telegraph company, or upon facsimile transmission. Filing by other means is complete as of the time of delivery to the Rulemakings and Adjudications Staff of the Office of the Secretary.

(c) Each document submitted for filing in an adjudication subject to this part, other than an exhibit, must be legibly typed, must bear the docket number and the title of the proceeding, and, if it is the first document filed by that participant, must designate the name and address of a person upon whom service can be made. The document also must be signed in accordance with §2.708(c). A document, other than correspondence, must be filed in an original and two conforming copies. Documents filed by telegram are governed by §2.708(f). A document that fails to conform to these requirements may be refused acceptance for filing and may be returned with an indication of the reason for nonacceptance. Any document tendered but not accepted for filing may not be entered in the docket.

(d) Computation of time and extension and reduction of time limits is done in accordance with §§2.710–2.711.

(e) A request for a hearing or petition for leave to intervene must be served in accordance with §2.712 and §2.1205(f) and (R). All other documents issued by the presiding officer or the Commission or offered for filing are served in accordance with §2.712.

[54 FR 8276, Feb. 28, 1989, as amended at 61 FR 39297, July 29, 1996; 62 FR 27495, May 20, 1997]

§2.1205 Request for a hearing; petition for leave to intervene.

(a) Any person whose interest may be affected by a proceeding for the grant, transfer, renewal, or licensee-initiated amendment of a license subject to this subpart may file a request for a hearing.

(b) An applicant for a license, a license amendment, a license transfer, or a license renewal who is issued a notice of proposed denial or a notice of denial

and who desires a hearing shall file the request for the hearing within the time specified in §2.103 in all cases. An applicant may include in the request for hearing a request that the presiding officer recommend to the Commission that procedures other than those authorized under this subpart be used in the proceeding, provided that the applicant identifies the special factual circumstances or issues which support the use of other procedures.

(c) For amendments of Part 50 licenses under §2.1201(a)(3), a notice of receipt of the application, with reference to the opportunity for a hearing under the procedures set forth in this subpart, must be published in the FEDERAL REGISTER at least 30 days prior to issuance of the requested amendment by the Commission.

(d) A person, other than an applicant, shall file a request for a hearing within—

(1) Thirty days of the agency's publication in the FEDERAL REGISTER of a notice referring or relating to an application or the licensing action requested by an application, which must include a reference to the opportunity for a hearing under the procedures set forth in this subpart. With respect to an amendment described in §2.1201(a)(3), other than the one to terminate the license, the Commission, prior to issuance of the requested amendment, will follow the procedures in §50.91 and §50.92(c) to the extent necessary to make a determination on whether the amendment involves a significant hazards consideration. If the Commission finds there are significant hazards considerations involved in the requested amendment, the amendment will not be issued until any hearings under this paragraph are completed.

(2) If a FEDERAL REGISTER notice is not published in accordance with paragraph (d)(1), the earliest of—

(i) Thirty days after the requester receives actual notice of a pending application, or

(ii) Thirty days after the requester receives actual notice of an agency action granting an application in whole or in part, or

(iii) One hundred and eighty days after agency action granting an application in whole or in part.

(e) The request for a hearing filed by a person other than an applicant must describe in detail—

(1) The interest of the requestor in the proceeding;

(2) How the interests may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in paragraph (h) of this section;

(3) The requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and

(4) The circumstances establishing that the request for a hearing is timely in accordance with paragraph (d) of this section.

(f) Each request for a hearing must be served, by delivering it personally or by mail to—

(1) The applicant (unless the requestor is the applicant); and

(2) The NRC staff, by delivery to the Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, or by mail addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

(g) Within ten (10) days of service of a request for a hearing filed under paragraph (c) of this section, the applicant may file an answer. The NRC staff, if it chooses or is ordered to participate as a party in accordance with §2.1213, may file an answer to a request for a hearing within ten (10) days of the designation of the presiding officer.

(h) In ruling on a request for a hearing filed under paragraph (d) of this section, the presiding officer shall determine that the specified areas of concern are germane to the subject matter of the proceeding and that the petition is timely. The presiding officer also shall determine that the requestor meets the judicial standards for standing and shall consider, among other factors—

(1) The nature of the requestor's right under the Act to be made a party to the proceeding;

(2) The nature and extent of the requestor's property, financial, or other interest in the proceeding; and

(3) The possible effect of any order that may be entered in the proceeding upon the requestor's interest.

(i) If a hearing request filed under paragraph (b) of this section is granted, the applicant and the NRC staff shall be parties to the proceeding. If a hearing request filed under paragraph (c) or (d) of this section is granted, the requestor shall be a party to the proceeding along with the applicant and the NRC staff, if the NRC staff chooses or is ordered to participate as a party in accordance with §2.1213.

(j) If a request for hearing is granted and a notice of the kind described in paragraph (d)(1) previously has not been published in the FEDERAL REGISTER, a notice of hearing must be published in the FEDERAL REGISTER stating—

(1) The time, place, and nature of the hearing;

(2) The authority under which the hearing is to be held;

(3) The matters of fact and law to be considered;

(4) The time within which any other person whose interest may be affected by the proceeding may petition for leave to intervene, as specified in paragraph (j) of this section; and

(5) The time within which a request to participate under §2.1211(b) must be filed.

(k) Any petition for leave to intervene must be filed within 30 days of the date of publication of the notice of hearing. The petition must set forth the information required under paragraph (e) of this section.

(l) A petition for leave to intervene must be served upon the applicant. The petition also must be served upon the NRC staff—

(i) By delivery to the Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(ii) By mail addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

(2) Within ten (10) days of service of a petition for leave to intervene, the applicant and the NRC staff, if the staff chooses or is ordered to participate as a party in accordance with §2.1213, may file an answer.

(3) Thereafter, the petition for leave to intervene must be ruled upon by the presiding officer, taking into account the matters set forth in paragraph (h) of this section.

(4) If the petition is granted, the petitioner becomes a party to the proceeding.

(l)(1) A request for a hearing or a petition for leave to intervene found by the presiding officer to be untimely under paragraph (d) or (k) of this section will be entertained only upon determination by the Commission or the presiding officer that the requestor or petitioner has established that—

(i) The delay in filing the request for a hearing or the petition for leave to intervene was excusable; and

(ii) The grant of the request for a hearing or the petition for leave to intervene will not result in undue prejudice or undue injury to any other participant in the proceeding, including the applicant and the NRC staff, if the staff chooses or is ordered to participate as a party in accordance with §2.1213.

(2) If the request for a hearing on the petition for leave to intervene is found to be untimely and the requestor or petitioner fails to establish that it otherwise should be entertained on the paragraph (l)(1) of this section, the request or petition will be treated as a petition under §2.206 and referred for appropriate disposition.

(m) The filing or granting of a request for a hearing or petition for leave to intervene need not delay NRC staff action regarding an application for a licensing action covered by this subpart.

(n) An order granting a request for a hearing or a petition for leave to intervene may condition or limit participation in the interest of avoiding repetitive factual presentations and argument.

(o) If the presiding officer denies a request for a hearing or a petition for leave to intervene in its entirety, the action is appealable within ten (10) days of service of the order on the question whether the request for a hearing or the petition for leave to intervene should have been granted in whole or in part. If a request for a hearing or a petition for leave to intervene is granted, parties other than the requestor or petitioner may appeal

that action within ten (10) days of service of the order on the question whether the request for a hearing or the petition for leave to intervene should have been denied in its entirety. An appeal may be taken by filing and serving upon all parties a statement that succinctly sets out, with supporting argument, the errors alleged. The appeal may be supported or opposed by any party by filing a counter-statement within fifteen (15) days of the service of the appeal brief.

[54 FR 8276, Feb. 28, 1989, as amended at 55 FR 36806, Sept. 7, 1990; 59 FR 29189, June 6, 1994; 61 FR 39297, July 29, 1996]

§2.1207 Designation of presiding officer.

(a) Unless otherwise ordered by the Commission or as provided in paragraph (b) of this section, within ten (10) days of receiving from the Office of the Secretary a request for a hearing relating to a licensing proceeding covered by this subpart, the Chairman of the Atomic Safety and Licensing Board Panel shall issue an order designating a single member of the panel to rule on the request for a hearing and, if necessary, to serve as the presiding officer to conduct the hearing.

(b) For any request for hearing relating to an application under 10 CFR part 70 to receive and store unirradiated fuel at the site of a production or utilization facility that also is the subject of a proceeding under subpart G of this part for the issuance of an operating license, within ten (10) days of receiving from the Office of the Secretary a request for a hearing the Chairman of the Atomic Safety and Licensing Board Panel shall issue an order designating a Licensing Board conducting the operating license proceeding to rule on the request for a hearing and, if necessary, to conduct the hearing in accordance with this subpart. Upon certification to the Commission by the Licensing Board designated to conduct the hearing that the matters presented for adjudication by the parties with respect to the part 70 application are substantially the same as those being heard in the pending proceeding under 10 CFR part 50, the Licensing Board may conduct the hearing in accordance with the procedures in subpart G.

179-032 O—98——5

the matters set forth in paragraph (h) of this section.

(4) If the petition is granted, the petitioner becomes a party to the proceeding.

(l)(1) A request for a hearing or a petition for leave to intervene found by the presiding officer to be untimely under paragraph (d) or (k) of this section will be entertained only upon determination by the Commission or the presiding officer that the requestor or petitioner has established that—

(i) The delay in filing the request for a hearing or the petition for leave to intervene was excusable; and

(ii) The grant of the request for a hearing or the petition for leave to intervene will not result in undue prejudice or undue injury to any other participant in the proceeding, including the applicant and the NRC staff, if the staff chooses or is ordered to participate as a party in accordance with §2.1213.

(2) If the request for a hearing on the petition for leave to intervene is found to be untimely and the requestor or petitioner fails to establish that it otherwise should be entertained on the paragraph (l)(1) of this section, the request or petition will be treated as a petition under §2.206 and referred for appropriate disposition.

(m) The filing or granting of a request for a hearing or petition for leave to intervene need not delay NRC staff action regarding an application for a licensing action covered by this subpart.

(n) An order granting a request for a hearing or a petition for leave to intervene may condition or limit participation in the interest of avoiding repetitive factual presentations and argument.

(o) If the presiding officer denies a request for a hearing or a petition for leave to intervene in its entirety, the action is appealable within ten (10) days of service of the order on the question whether the request for a hearing or the petition for leave to intervene should have been granted in whole or in part. If a request for a hearing or a petition for leave to intervene is granted, parties other than the requestor or petitioner may appeal

that action within ten (10) days of service of the order on the question whether the request for a hearing or the petition for leave to intervene should have been denied in its entirety. An appeal may be taken by filing and serving upon all parties a statement that succinctly sets out, with supporting argument, the errors alleged. The appeal may be supported or opposed by any party by filing a counter-statement within fifteen (15) days of the service of the appeal brief.

[54 FR 8276, Feb. 28, 1989, as amended at 55 FR 36806, Sept. 7, 1990; 59 FR 29189, June 6, 1994; 61 FR 39297, July 29, 1996]

§2.1207 Designation of presiding officer.

(a) Unless otherwise ordered by the Commission or as provided in paragraph (b) of this section, within ten (10) days of receiving from the Office of the Secretary a request for a hearing relating to a licensing proceeding covered by this subpart, the Chairman of the Atomic Safety and Licensing Board Panel shall issue an order designating a single member of the panel to rule on the request for a hearing and, if necessary, to serve as the presiding officer to conduct the hearing.

(b) For any request for hearing relating to an application under 10 CFR part 70 to receive and store unirradiated fuel at the site of a production or utilization facility that also is the subject of a proceeding under subpart G of this part for the issuance of an operating license, within ten (10) days of receiving from the Office of the Secretary a request for a hearing the Chairman of the Atomic Safety and Licensing Board Panel shall issue an order designating a Licensing Board conducting the operating license proceeding to rule on the request for a hearing and, if necessary, to conduct the hearing in accordance with this subpart. Upon certification to the Commission by the Licensing Board designated to conduct the hearing that the matters presented for adjudication by the parties with respect to the part 70 application are substantially the same as those being heard in the pending proceeding under 10 CFR part 50, the Licensing Board may conduct the hearing in accordance with the procedures in subpart G.

§2.1209 Power of presiding officer.

A presiding officer has the duty to conduct a fair and impartial hearing according to law, to take appropriate action to avoid delay, and to maintain order. The presiding officer has all powers necessary to those ends, including the power to—

(a) Regulate the course of the hearing and the conduct of the participants;

(b) Dispose of procedural requests or similar matters;

(c) Hold conferences before or during the hearing for settlement, simplification of the issues, or any other proper purpose;

(d) Certify questions to the Commission for determination, either in the presiding officer's discretion or on direction of the Commission;

(e) Reopen a closed record for the reception of further information at any time prior to initial decision in accordance with §2.734;

(f) Administer oaths and affirmations;

(g) Issue initial decisions;

(h) Issue subpoenas requiring the attendance and testimony of witnesses at the hearing or the production of documents for the hearing;

(i) Receive written or oral evidence and take official notice of any fact in accordance with §2.743(i);

(j) Appoint special assistants from the Atomic Safety and Licensing Board Panel in accordance with §2.722;

(k) Recommend to the Commission that procedures other than those authorized under this subpart be used in a particular proceeding; and

(l) Take any other action consistent with the Act and this chapter.

[54 FR 8276, Feb. 28, 1989, as amended at 56 FR 29411, June 27, 1991]

§2.1211 Participation by a person not a party.

(a) The presiding officer may permit a person who is not a party to make a limited appearance in order to state his or her views on the issues. Limited appearances may be in writing or oral, at the discretion of the presiding officer, and are governed by rules adopted by the presiding officer. A limited appearance statement is not to be considered

179-032 O—98——5

part of the decisional record under §2.1251(c).

(b) Within 30 days of an order granting a request for a hearing made under §2.1205 (b)–(d) or, in instances when it is published, within 30 days of notice of hearing issued under §2.1205(j), the representative of the interested State, county, municipality, or an agency thereof, may request an opportunity to participate in a proceeding under this subpart. The request for an opportunity to participate must state with reasonable specificity the requestor's areas of concern about the licensing activity that is the subject matter of the proceeding. Upon receipt of a request that is filed in accordance with these time limits and that specifies the requestor's areas of concern, the presiding officer shall afford the representative a reasonable opportunity to make written and oral presentations in accordance with §§2.1233 and 2.1235, without requiring the representative to take a position with respect to the issues. Participants under this subsection may notice an appeal of an initial decision in accordance with §2.1253 with respect to any issue on which they participate.

[54 FR 8276, Feb. 28, 1989, as amended at 61 FR 39298, July 29, 1996]

§2.1213 Role of the NRC staff.

If a hearing request is filed under §2.1205(b), the NRC staff shall be a party to the proceeding. If a hearing request is filed under §2.1205 (c) or (d), within 10 days of the designation of a presiding officer pursuant to §2.1207, the NRC staff shall notify the presiding officer whether or not the staff desires to participate as a party to the adjudication. In addition, upon a determination by the presiding officer that the resolution of any issue in the proceeding would be aided materially by the staff's participation in the proceeding as a party, the presiding officer may order or permit the NRC staff to participate as a party with respect to that particular issue.

[61 FR 39298, July 29, 1996]

§2.1215 Appearance and practice.

(a) An individual may appear in an adjudication under this subpart on his or her own behalf or by an attorney-at-law. Representation by an attorney-at-law is not necessary in order for an organization or a §2.1211(b) participant to appear in an adjudication conducted under this subpart. If the representative of an organization is not an attorney-at-law, he or she shall be a member or officer of the organization represented. Upon request of the presiding officer, an individual acting as a representative shall provide appropriate information establishing the basis of his or her authority to act in a representational capacity.

(b) Any action to reprimand, censure, or suspend a party, a §2.1211(b) participant, or the representative of a party or a §2.1211(b) participant must be in accordance with the procedures in §2.713(c).

HEARINGS

§2.1231 Hearing file; prohibition on discovery.

(a) Within thirty (30) days of the presiding officer's entry of an order granting a request for a hearing, the NRC staff shall file in the docket, present to the presiding officer, and make available to the applicant and any other party to the proceeding a hearing file. Thereafter, within ten (10) days of the date a petition for leave to intervene or a request to participate under §2.1211(b) is granted, the NRC staff shall make the hearing file available to the petitioner or the §2.1211(b) participant.

(1) The hearing file must be made available to the applicant and any other party or §2.1211(b) participant to the proceeding either by—

(i) Service in accordance with §2.1203(e); or

(ii) Placing the file in an established local public document room in the vicinity of the principal location where nuclear material that is the subject of a proceeding under this subpart will be possessed, and informing the applicant, party, or §2.1211(b) participant in writing of its action and the location of the file. If an established local public document room does not exist, the NRC staff will arrange for the documents contained in the hearing file, along with any other material docketed in accordance with §2.1203, to be made available for public inspection and copying during the course of the adjudication in a library or other facility that is accessible to the general public during regular business hours and is in the vicinity of the principal location where the nuclear material that is the subject of the proceeding will be possessed.

(2) The hearing file also must be made available for public inspection and copying during regular business hours at the NRC Public Document Room in Washington, DC.

(b) The hearing file will consist of the application and any amendment thereto, any NRC environmental impact statement or assessment relating to the application, and any NRC report and any correspondence between the applicant and the NRC that is relevant to the application. Hearing file documents already in an established local public document room or the NRC Public Document Room when the hearing request is granted may be incorporated into the hearing file at those locations by a reference indicating where at those locations the documents can be found. The presiding officer shall rule upon any issue regarding the appropriate materials for the hearing file.

(c) The NRC staff has a continuing duty to keep the hearing file up to date with respect to the materials set forth in paragraph (b) of this section and to provide those materials for the docket, the presiding officer, and the applicant or any party or §2.1211(b) participant in a manner consistent with the way the hearing file was made available initially under paragraph (a).

(d) A party or §2.1211(b) participant may not seek discovery from any other party, §2.1211(b) participant, or the NRC or its personnel, whether by document production, deposition, interrogatories, or otherwise.

§2.1233 Written presentations; written questions.

(a) After publication of a notice of hearing in accordance with §2.1205(i) and after the NRC staff has made the hearing file available in accordance with §2.1231, the parties and §2.1211(b) participants shall be afforded the opportunity to submit, under oath or af-

or her own behalf or by an attorney-at-law. Representation by an attorney-at-law is not necessary in order for an organization or a §2.1211(b) participant to appear in an adjudication conducted under this subpart. If the representative of an organization is not an attorney-at-law, he or she shall be a member or officer of the organization represented. Upon request of the presiding officer, an individual acting as a representative shall provide appropriate information establishing the basis of his or her authority to act in a representational capacity.

(b) Any action to reprimand, censure, or suspend a party, a §2.1211(b) participant, or the representative of a party or a §2.1211(b) participant must be in accordance with the procedures in §2.713(c).

HEARINGS

§2.1231 Hearing file; prohibition on discovery.

(a) Within thirty (30) days of the presiding officer's entry of an order granting a request for a hearing, the NRC staff shall file in the docket, present to the presiding officer, and make available to the applicant and any other party to the proceeding a hearing file. Thereafter, within ten (10) days of the date a petition for leave to intervene or a request to participate under §2.1211(b) is granted, the NRC staff shall make the hearing file available to the petitioner or the §2.1211(b) participant.

(1) The hearing file must be made available to the applicant and any other party or §2.1211(b) participant to the proceeding either by—

(i) Service in accordance with §2.1203(e); or

(ii) Placing the file in an established local public document room in the vicinity of the principal location where nuclear material that is the subject of a proceeding under this subpart will be possessed, and informing the applicant, party, or §2.1211(b) participant in writing of its action and the location of the file. If an established local public document room does not exist, the NRC staff will arrange for the documents contained in the hearing file, along with any other material docketed in accordance with §2.1203, to be made available for public inspection and copying during the course of the adjudication in a library or other facility that is accessible to the general public during regular business hours and is in the vicinity of the principal location where the nuclear material that is the subject of the proceeding will be possessed.

(2) The hearing file also must be made available for public inspection and copying during regular business hours at the NRC Public Document Room in Washington, DC.

(b) The hearing file will consist of the application and any amendment thereto, any NRC environmental impact statement or assessment relating to the application, and any NRC report and any correspondence between the applicant and the NRC that is relevant to the application. Hearing file documents already in an established local public document room or the NRC Public Document Room when the hearing request is granted may be incorporated into the hearing file at those locations by a reference indicating where at those locations the documents can be found. The presiding officer shall rule upon any issue regarding the appropriate materials for the hearing file.

(c) The NRC staff has a continuing duty to keep the hearing file up to date with respect to the materials set forth in paragraph (b) of this section and to provide those materials for the docket, the presiding officer, and the applicant or any party or §2.1211(b) participant in a manner consistent with the way the hearing file was made available initially under paragraph (a).

(d) A party or §2.1211(b) participant may not seek discovery from any other party, §2.1211(b) participant, or the NRC or its personnel, whether by document production, deposition, interrogatories, or otherwise.

§2.1233 Written presentations; written questions.

(a) After publication of a notice of hearing in accordance with §2.1205(i) and after the NRC staff has made the hearing file available in accordance with §2.1231, the parties and §2.1211(b) participants shall be afforded the opportunity to submit, under oath or affirmation, written presentations of their arguments and documentary data, informational material, and other supporting written evidence at the time or times and in the sequence the presiding officer establishes by appropriate order. The presiding officer also may, on his or her initiative, submit written questions to the parties to be answered in writing, under oath or affirmation, and supported by appropriate documentary data, informational material, or other written evidence.

(b) In a hearing initiated under §2.1205(b), the initial written presentation of the applicant that is issued a notice of proposed denial or a notice of denial must describe in detail any deficiency or omission in the agency's denial or proposed denial of its application and what relief is sought with respect to each deficiency or omission.

(c) In a hearing initiated under §2.1205(d), the initial written presentation of a party that requested a hearing or petitioned for leave to intervene must describe in detail any deficiency or omission in the license application, with references to any particular section or portion of the application considered deficient, give a detailed statement of reasons why any particular sections or portion is deficient or why an omission is material, and describe in detail what relief is sought with respect to each deficiency or omission.

(d) A party or §2.1211(b) participant making an initial written presentation under this section shall submit with its presentation or identify by reference to a generally available publication or source, such as the hearing file, all documentary data, informational material, or other written evidence upon which it relies to support or illustrate each omission or deficiency complained of. Thereafter, additional documentary data, informational material, or other written evidence may be submitted or referenced by any party, other than the NRC staff, or by any §2.1211(b) participant in a written presentation or in response to a written question only as the presiding officer, in his or her discretion, permits.

(e) Strict rules of evidence do not apply to written submissions under this section, but the presiding officer

may, on motion or on the presiding officer's own initiative, strike any portion of a written presentation or a response to a written question that is cumulative, irrelevant, immaterial, or unreliable.

[54 FR 8276, Feb. 28, 1989, as amended at 61 FR 39298, July 29, 1996]

§ 2.1235 Oral presentations; oral questions.

(a) Upon a determination that it is necessary to create an adequate record for decision, in his or her discretion the presiding officer may allow or require oral presentations by any party or § 2.1211(b) participant, including testimony by witnesses. Oral presentations are subject to any appropriate time limits the presiding officer imposes. Responsibility for the conduct of the examination of any witness rests with the presiding officer who may allow a party or § 2.1211(b) participant to propose questions for the presiding officer to pose to a witness.

(b) Oral presentations and responses to oral questioning to be relied upon as oral evidence must be given under oath or affirmation. All oral presentations or oral questioning must be stenographically reported and, except as requested pursuant to section 181 of the Act, must be public unless otherwise ordered by the Commission.

(c) Strict rules of evidence do not apply to oral submissions under this section, but the presiding officer may, on motion or on the presiding officer's own initiative, strike any portion of an oral presentation or a response to oral questioning that is cumulative, irrelevant, immaterial, or unreliable.

[54 FR 8279, Feb. 28, 1989; 54 FR 53035, Dec. 26, 1989]

§ 2.1237 Motions; burden of proof.

(a) Motions presented in the proceeding must be presented and disposed of in accordance with §§ 2.730 (a)–(g).

(b) Unless otherwise ordered by the presiding officer, the applicant or the proponent of an order has the burden of proof.

§ 2.1239 Consideration of Commission rules and regulations in informal adjudications.

(a) Except as provided in paragraph (b) of this section, any regulation of the Commission issued in its program for the licensing and regulation of production and utilization facilities, source material, special nuclear material, or byproduct material may not be challenged in any adjudication subject to this subpart.

(b) A party to an adjudication subject to this subpart may petition that the application of a Commission regulation specified in paragraph (a) of this section be waived or an exception made for the particular proceeding. The sole ground for a request for waiver or exception must be that special circumstances exist so that application of the regulation to the subject matter of the proceeding would not serve the purposes for which the regulation was adopted. In the absence of a prima facie showing of special circumstances, the presiding officer may not further consider the matter. If the presiding officer determines that a prima facie showing has been made, he or she shall certify directly to the Commission itself for determination the matter of whether special circumstances support a waiver or an exception and whether a waiver or an exception should be granted. The Commission's determination shall be made after any further proceeding the Commission deems appropriate.

§ 2.1241 Settlement of proceedings.

The fair and reasonable settlement of proceedings subject to this subpart is encouraged. A settlement must be approved by the presiding officer or the Commission as appropriate in order to be binding in the proceeding.

[56 FR 29411, June 27, 1991]

Initial Decision, Commission Review, and Final Decision

§ 2.1251 Initial decision and its effect.

(a) Unless the Commission directs that the record be certified to it in accordance with paragraph (b) of this section, the presiding officer shall render

an initial decision after completion of an informal hearing under this subpart. That initial decision constitutes the final action of the Commission thirty (30) days after the date of issuance, unless any party petitions for Commission review in accordance with § 2.786 or the Commission takes review of the decision sua sponte.

(b) The Commission may direct that the presiding officer certify the record to it without an initial decision and may omit an initial decision and prepare a final decision upon a finding that due and timely execution of its functions so requires.

(c) An initial decision must be in writing and must be based only upon information in the record or facts officially noticed. The record must include all information submitted in the proceeding with respect to which all parties have been given reasonable prior notice and an opportunity to comment. The initial decision must include—

(1) Findings, conclusions, and rulings, with the reasons or basis for them, on all material issues of fact, law, or discretion presented on the record;

(2) The appropriate ruling, order, or denial of relief with its effective date; and

(3) The time within which a petition for review may be filed, the time within which any answer to a petition for review may be filed, and the date when the decision becomes final in the absence of the Commission taking review of the decision.

(d) Matters not put into controversy by the parties may not be examined and decided by the presiding officer. If the presiding officer believes that a serious safety, environmental, or common defense and security matter exists that has not been placed in controversy, the presiding officer shall advise the Commission promptly of the basis for that view, and the Commission may take appropriate action.

(e) Pending review and final decision by the Commission, an initial decision resolving all issues before the presiding officer in favor of authorizing licensing action subject to this subpart is immediately effective upon issuance except—

§ 2.1239 Consideration of Commission rules and regulations in informal adjudications.

(a) Except as provided in paragraph (b) of this section, any regulation of the Commission issued in its program for the licensing and regulation of production and utilization facilities, source material, special nuclear material, or byproduct material may not be challenged in any adjudication subject to this subpart.

(b) A party to an adjudication subject to this subpart may petition that the application of a Commission regulation specified in paragraph (a) of this section be waived or an exception made for the particular proceeding. The sole ground for a request for waiver or exception must be that special circumstances exist so that application of the regulation to the subject matter of the proceeding would not serve the purposes for which the regulation was adopted. In the absence of a prima facie showing of special circumstances, the presiding officer may not further consider the matter. If the presiding officer determines that a prima facie showing has been made, he or she shall certify directly to the Commission itself for determination the matter of whether special circumstances support a waiver or an exception and whether a waiver or an exception should be granted. The Commission's determination shall be made after any further proceeding the Commission deems appropriate.

§ 2.1241 Settlement of proceedings.

The fair and reasonable settlement of proceedings subject to this subpart is encouraged. A settlement must be approved by the presiding officer or the Commission as appropriate in order to be binding in the proceeding.

[56 FR 29411, June 27, 1991]

INITIAL DECISION, COMMISSION REVIEW, AND FINAL DECISION

§ 2.1251 Initial decision and its effect.

(a) Unless the Commission directs that the record be certified to it in accordance with paragraph (b) of this section, the presiding officer shall render an initial decision after completion of an informal hearing under this subpart. That initial decision constitutes the final action of the Commission thirty (30) days after the date of issuance, unless any party petitions for Commission review in accordance with § 2.786 or the Commission takes review of the decision sua sponte.

(b) The Commission may direct that the presiding officer certify the record to it without an initial decision and may omit an initial decision and prepare a final decision upon a finding that due and timely execution of its functions so requires.

(c) An initial decision must be in writing and must be based only upon information in the record or facts officially noticed. The record must include all information submitted in the proceeding with respect to which all parties have been given reasonable prior notice and an opportunity to comment. The initial decision must include—

(1) Findings, conclusions, and rulings, with the reasons or basis for them, on all material issues of fact, law, or discretion presented on the record;

(2) The appropriate ruling, order, or denial of relief with its effective date; and

(3) The time within which a petition for review may be filed, the time within which any answer to a petition for review may be filed, and the date when the decision becomes final in the absence of the Commission taking review of the decision.

(d) Matters not put into controversy by the parties may not be examined and decided by the presiding officer. If the presiding officer believes that a serious safety, environmental, or common defense and security matter exists that has not been placed in controversy, the presiding officer shall advise the Commission promptly of the basis for that view, and the Commission may take appropriate action.

(e) Pending review and final decision by the Commission, an initial decision resolving all issues before the presiding officer in favor of authorizing licensing action subject to this subpart is immediately effective upon issuance except—

(1) As provided in any order issued in accordance with § 2.1263 that stays the effectiveness of an initial decision; or

(2) As otherwise provided by the Commission in special circumstances.

(f) Following an initial decision resolving all issues in favor of the licensing action as specified in paragraph (e) of this section, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, notwithstanding the filing of a petition for review or pendency of any review taken by the Commission pursuant to § 2.786, shall take the appropriate licensing action upon making the appropriate licensing findings promptly, except as may be provided pursuant to paragraph (e)(1) or (2) of this section.

[54 FR 8280, Feb. 28, 1989; 54 FR 53035, Dec. 26, 1989; 56 FR 29411, June 27, 1991]

§ 2.1253 Petitions for review of initial decisions.

Parties and § 2.1211(b) participants may petition for review of an initial decision under this subpart in accordance with the procedures set out in §§ 2.786 and 2.763 or the Commission may review the decision on its own motion. Commission review will be conducted in accordance with those procedures the Commission deems appropriate. The filing of a petition for review is mandatory for a party to exhaust its administrative remedies before seeking judicial review.

[56 FR 29411, June 27, 1991]

§ 2.1259 Final decision; petition for reconsideration.

(a) Commission action to render a final decision must be in accordance with § 2.770.

(b) The provisions of § 2.771 govern the filing of petitions for reconsideration.

§ 2.1261 Authority of the Secretary to rule on procedural matters.

The Secretary or the Assistant Secretary may rule on procedural matters relating to proceedings conducted by the Commission itself under this subpart to the same extent they can do so under § 2.772 for proceedings under subpart G.

§ 2.1263 Stays of NRC staff licensing actions or of decisions of a presiding officer or the Commission pending hearing or review.

Applications for a stay of any decision or action of the Commission, a presiding officer, or any action by the NRC staff in issuing a license in accordance with §2.1205(m) are governed by §2.788, except that any request for a stay of staff licensing action pending completion of an adjudication under this subpart must be filed at the time a request for a hearing or petition to intervene is filed or within 10 days of the staff's action, whichever is later. A request for a stay of a staff licensing action must be filed with the adjudicatory decisionmaker before which the licensing proceeding is pending.

[61 FR 39298, July 29, 1996]

APPENDIX A TO PART 2—STATEMENT OF GENERAL POLICY AND PROCEDURE: CONDUCT OF PROCEEDINGS FOR THE ISSUANCE OF CONSTRUCTION PERMITS AND OPERATING LICENSES FOR PRODUCTION AND UTILIZATION FACILITIES FOR WHICH A HEARING IS REQUIRED UNDER SECTION 189A OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED*

The following statement of general policy and procedure explains in detail the procedures which the Nuclear Regulatory Commission expects to be followed by atomic safety and licensing boards in the conduct of proceedings relating to the issuance of construction permits for nuclear power and test reactors and other production or utilization facilities for which a hearing is mandatory under section 189a of the Atomic Energy Act of 1954, as amended (the Act) and the Energy Reorganization Act of 1974.[1] The provisions are also applicable to proceedings for the issuance of operating licenses for such facilities, except as the context would otherwise indicate, or except as indicated in section VIII. Section VIII sets out the procedures specifically applicable to operating license proceedings. The Statement reflects the Commission's intent that such proceedings be conducted expeditiously and its concern that its procedures maintain sufficient flexibility to accommodate that objective. This position is founded upon the recognition that fairness to all the parties in such cases and the obligation of administrative agencies to conduct their functions with efficiency and economy, require that Commission adjudications be conducted without unnecessary delays. These factors take on added importance in nuclear power reactor licensing proceedings where the growing national need for electric power and the companion need for protecting the quality of the environment call for decision making which is both sound and timely. The Commission expects that its responsibilities under the Atomic Energy Act of 1954, the National Environmental Policy Act of 1969 and other applicable statutes, as set out in the statement which follows, will be carried out in a manner consistent with this position in the overall public interest.

Atomic safety and licensing boards are appointed from time to time by the Commission or the Chairman of the Atomic Safety and Licensing Board Panel to conduct hearings in licensing cases under the authority of section 191 of the Act. Section 191 authorizes the Commission to establish one or more atomic safety and licensing boards to conduct public hearings and to make intermediate or final decisions in administrative proceedings relating to granting, suspending, revoking or amending licenses issued by the Commission. It requires that each board consist of one member who is qualified in the conduct of administrative proceedings and two members who have such technical or other qualifications as the Commission deems appropriate to the issues to be decided. Members of each board may be appointed by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel from a panel selected from private life, the staff of the Commission or other Federal agencies.

An Atomic Safety and Licensing Board may at its discretion appoint special assistants to the Board from the membership of the Atomic Safety and Licensing Board Panel established by the Commission. These special assistants are to be employed to facilitate the hearing process and improve the quality of the record produced for review. The special assistants may serve as technical interrogators in their individual fields of expertise, alternate Atomic Safety and Licensing Board members to sit with the Board and participate in the evidentiary sessions on the issue for which the alternate members were designated, Special Masters to hear evidentiary presentations by the parties on specific technical matters upon the consent of all parties, or informal consultants to brief the board prior to the hearing on the general

*In the event of any conflict between the provisions of this appendix and any section of this part, the section governs.

[1]Except as the context may otherwise indicate, this statement is also generally applicable to licensing proceedings of the type described in the statement which may be conducted by a hearing examiner as the presiding officer.

technical background of subjects involving complex issues. The term "alternate board member" as a "special assistant" within the meaning of 10 CFR 2.722(a)(3) should not be confused with the use of the term "alternate" in 10 CFR 2.721(b). In the latter situation the "alternate" is a substitute for a member of a Board who becomes unavailable. As a special assistant, the "alternate" sits with the three-member Board and not instead of the Board or any of its members.

I. PRELIMINARY MATTERS

(a) A public hearing is announced by the issuance of a notice of hearing, published in the FEDERAL REGISTER as soon as practicable after the application has been docketed, signed by the Secretary of the Commissionstating the nature of the hearing and the issues to be considered. The time and place of the first prehearing conference pursuant to §2.751a will ordinarily be stated in the notice of hearing. Unless the initial notice of hearing states the time and place of the hearing, and the Chairman and other members of the Atomic Safety and Licensing Board that will conduct the hearing, those matters will be the subject of further notice in the FEDERAL REGISTER after publication of the initial notice of hearing. It is the Commission's policy and practice to begin the evidentiary hearing in the vicinity of the site of the proposed facility. The notice of hearing also states the procedures whereby persons may seek to intervene or make a limited appearance and explains the differences between those forms of participation in the proceeding, and states the times and places of the availability, in an appropriate office near the site of the proposed facility, of the notice of hearing, an updated copy of the application, the report of the Advisory Committee on Reactor Safeguards (ACRS), the staff safety evaluation, the applicant's environmental report, the Commission's environmental impact statement, the proposed construction permit or operating license and the transcripts of the prehearing conference and the hearing.

(b) In fixing the time and place of any conference, including prehearing conferences, or of any adjourned session of the evidentiary hearing, due regard shall be had for the convenience and necessity of the parties, petitioners for leave to intervene, or the representatives of such persons, as well as of the Board members, the nature of such conference or adjourned session, and the public interest. Adjourned sessions of hearings may be held in the Washington, DC area if all parties so stipulate. If the parties disagree, and any party considers that there are valid reasons for holding such session in the Washington, DC area, the matter should be referred to the Commission for resolution.

ATTACHMENT 7

Table 8.7 Thorium Series (4n)[a]

(Personal communication L. Slaback after Kocher 1981 and ICRP Report No. 38, 1983. In case of discrepancy, ICRP value given)

Nuclide	Historical Name	Half-life	Major Radiation Energies (MeV) and Intensities[b]					
			α		β		γ	
			MeV	%	MeV	%	MeV	%
$^{232}_{90}Th$	Thorium	1.405×10^{10} y	3.83	0.2			.059	.19
↓			3.95	23			.126	.04
			4.01	76.8				
$^{228}_{88}Ra$	Mesothorium I	5.75 y			.0389	100	.0067	6×10^{-5}
↓								
$^{228}_{89}Ac$	Mesothorium II	6.13 h			.983	7	.338	11.4
↓					1.014	6.6	.911	27.7
					1.115	3.4	.969	16.6
					1.17	32	1.588	3.5
					1.74	12		
					2.08	8		
					(+33 more βs)			
$^{228}_{90}Th$	Radiothorium	1.913 y	5.34	26.7			0.84	1.19
↓			5.42	72.4			.132	.11
							.166	.08
							.216	.27
$^{224}_{88}Ra$	Thorium X	3.66 d	5.45	4.9			.241	3.9
↓			5.686	95.1				
$^{220}_{86}Rn$	Emanation Thoron (Tn)	55.6 s	6.288	99.9			.55	.07
↓								
$^{216}_{84}Po$	Thorium A	.15 s	6.78	100			.128	.002
↓								
$^{212}_{82}Pb$	Thorium B	10.64 h			.158	5.2	.239	44.6
↓					.334	85.1	.300	3.4
					.573	9.9		
$^{212}_{83}Bi$	Thorium C	60.55 m	6.05	25	1.59	8	.040	1.0
↓			6.09	9.6	2.246	48.4	.727	11.8
							1.620	2.75
64.07% | 35.93%								
↓ $^{212}_{84}Po$	Thorium C'	305 ns	8.785	100				
↓ $^{208}_{81}Tl$	Thorium C"	3.07 m			1.28	25	.277	6.8
					1.52	21	.5108	21.6
					1.80	50	.583	85.8
							.860	12
↓	Thorium D	Stable					2.614	100
$^{208}_{82}Pb$								

a This expression describes the mass number of any member in this series, where n is an integer. For example: $^{232}_{90}Th$ (4n).....4(58) = 232

b Intensities refer to percentage of disintegrations of the nuclide itself, not to original parent of series. Gamma % in terms of observable emissions, not transitions.