APPENDIX A

ATSDR MINIMAL RISK LEVELS AND WORKSHEETS

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601 et seq.], as amended by the Superfund Amendments and Reauthorization Act (SARA) [Pub. L. 99–499], requires that the Agency for Toxic Substances and Disease Registry (ATSDR) develop jointly with the U.S. Environmental Protection Agency (EPA), in order of priority, a list of hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL); prepare toxicological profiles for each substance included on the priority list of hazardous substances; and assure the initiation of a research program to fill identified data needs associated with the substances.

The toxicological profiles include an examination, summary, and interpretation of available toxicological information and epidemiologic evaluations of a hazardous substance. During the development of toxicological profiles, Minimal Risk Levels (MRLs) are derived when reliable and sufficient data exist to identify the target organ(s) of effect or the most sensitive health effect(s) for a specific duration for a given route of exposure. An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure. MRLs are based on noncancer health effects only and are not based on a consideration of cancer effects. These substance-specific estimates, which are intended to serve as screening levels, are used by ATSDR health assessors to identify contaminants and potential health effects that may be of concern at hazardous waste sites. It is important to note that MRLs are not intended to define clean-up or action levels.

MRLs are derived for hazardous substances using the no-observed-adverse-effect level/uncertainty factor approach. They are below levels that might cause adverse health effects in the people most sensitive to such effects. MRLs are derived for acute (1–14 days), intermediate (15–364 days), and chronic (365 days and longer) durations and for the oral, inhalation, and external routes of exposure. Currently, MRLs for the dermal route of exposure are not derived because ATSDR has not yet identified a method suitable for this route of exposure. MRLs are generally based on the most sensitive end point considered to be of relevance to humans. Serious health effects (such as irreparable damage to the liver or kidneys, or birth defects) are not used as a basis for establishing MRLs. Exposure to a level above the MRL does not mean that adverse health effects will occur.

MRLs are intended only to serve as a screening tool to help public health professionals decide where to look more closely. They may also be viewed as a mechanism to identify those hazardous waste sites that are not expected to cause adverse health effects. Most MRLs contain a degree of uncertainty because of the lack of precise toxicological information on the people who might be most sensitive (e.g., infants, elderly, nutritionally or immunologically compromised) to the effects of hazardous substances. ATSDR uses a conservative (i.e., protective) approach to address this uncertainty consistent with the public health principle of prevention. Although human data are preferred, MRLs often must be based on animal studies because relevant human studies are lacking. In the absence of evidence to the contrary, ATSDR assumes that humans are more sensitive to the effects of hazardous substance than animals and that certain persons may be particularly sensitive. Thus, the resulting MRL may be as much as a hundredfold below levels that have been shown to be nontoxic in laboratory animals.

Proposed MRLs undergo a rigorous review process: Health Effects/MRL Workgroup reviews within the Division of Toxicology, expert panel peer reviews, and agencywide MRL Workgroup reviews, with participation from other federal agencies and comments from the public. They are subject to change as new information becomes available concomitant with updating the toxicological profiles. Thus, MRLs in the most recent toxicological profiles supersede previously published levels. For additional information regarding MRLs, please contact the Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, Mailstop E-29, Atlanta, Georgia 30333.

APPENDIX A

MINIMAL RISK LEVEL (MRL) WORKSHEET

Chemical name: Ionizing Radiation
CAS number: Multiple
Date: October 1, 1999
Profile status: Final
Route: [ ] Inhalation [ ] Oral [X] External
Duration: [X] Acute [ ] Intermediate [ ] Chronic
Species: Human

MRL: 4 [ ] mg/kg/day [ ] ppm [ ] mg/m^3 [X] mSv (400mrem)

References:

Schull WJ, Otake M and Yoshimaru H (1988). Effect on intelligence test score of prenatal exposure to ionizing radiation in Hiroshima and Nagasaki: A comparison of the T65DR and DS86 dosimetry systems.

Burt C. (1966). The genetic determination of differences in intelligence: A study of monozygotic twins reared together and apart. Brit. J. Psychol. 57 (1& 2): pp. 137-153

Experimental design:

Schull et al. (1988) study: Schull et al. (1988) evaluated the quantitative effect of exposure to ionizing radiation on the developing fetal and embryonic human brain. The end point measured was changes in intelligence test scores. The effects on individuals exposed *in utero* to the atomic bombing of Hiroshima and Nagasaki were based on the original PE86 samples (n=1759; data on available intelligence testing) and a clinical sample (n=1598). The original PE86 sample included virtually all prenatally exposed individuals who received tissue-absorbed doses of 0.50 Gy or more. There were many more individuals in the dose range 0-0.49 Gy in the PE86 sample than in the clinical sample. The clinical sample does not include children prenatally exposed at distances between 2,000-2,999 m in Hiroshima and Nagasaki. Children exposed at greater distances or not present in the city were selected as controls. In 1955-1956, Tanaka-B (emphasis on word-sense, arithmetic abilities, and the like which were associated with the more subtle processing of visual clues than their simple recognition and depended more on connectedness) and the Koga (emphasis on perception of spatial relationships) intelligence tests were conducted in Nagasaki and the Koga test in Hiroshima.

Burt (1966) study: This study determined differences in intelligence in monozygotic twins reared together (n=95) and apart (n=53). All tests conducted in school consisted of (1) a group test of intelligence containing both non-verbal and verbal items, (2) an individual test (the London Revision of the Terman-Binet Scale) used primarily for standardization and for doubtful cases, and (3) a set of performance tests, based on the Pitner-Paterson tests and standardization. The methods and standard remained much the same throughout the study. Some of the reasons for separation of the twins were given as follows: death of the mother (n=9), unable to bring them up properly, mother's poor health (n=12), unmarried (n=6), and economic difficulties. The children were brought up by parents or foster parents (occupation ranged from unskilled to professional). IQ scores in the study group ranged from 66 to 137. The standard deviation of the group of separated monozygotic twins was reported at 15.3 as compared to

15.0 of ordinary siblings. Twins brought up in different environments were compared with those brought up in similar circumstances.

Effects noted in study and corresponding doses:

Schull et al. (1986) study: No evidence of radiation-related effect on intelligence was observed among individuals exposed within 0-7 weeks after fertilization or in the 26th or subsequent weeks. The highest risk of radiation damage to the embryonic and fetal brain occurs 8-15 weeks after fertilization under both dosimetric systems. The regression of intelligence score on estimated DS86 uterine absorbed dose is linear with dose, the diminution in intelligence score is 21-29 points per Gy for the 8-15 week group and 10-26 points per Gy for the 16-25 week group. The results for 8-15 weeks applies regardless whether the mentally retarded individuals were included. The cumulative distribution of test scores suggested a progressive shift downwards in individual scores with increasing exposure. The mean IQ scores decrease significantly and systematically with uterine or fetal tissue dose within the 8-15 and 16-25 week groups.

In summary, analysis of intelligence test scores at 10-11 years of age of individuals exposed prenatally showed that:

- There is no evidence of a radiation-related effect on intelligence scores among those individuals exposed within 0-7 weeks of fertilization or in the 26th week of gestation and beyond;
- The cumulative distribution of test scores suggests a progressive shift downwards in intelligence scores with increasing exposure to ionizing radiation (dose-response relationship).
- The most sensitive group was the 8-15 weeks exposure group. The regression in intelligence scores was found to be linear, with 1 Gy dose resulting in a 21-29 point decline in intelligence scores.
- There was no indication of groups of individuals with differing sensitivities to radiation.

Burt (1966) study: The average intelligence of the twins measured on a conventional IQ scale (SD=15) was 97.8 for the separated monozygotes, 98.1 for monozygotes brought up together, 99.3 for the dizygotes as compared with 100.2 for the siblings, and 100.0 for the population as a whole. The difference of 0.3 IQ point between the separated and unseparated identical twins is considered a no-observed-adverse-effect level (NOAEL) for this study.

Dose endpoint used for MRL derivation:

[X] NOAEL [ ] LOAEL — 0.3 IQ point reduction in twins, between those raised together and those raised apart.

Uncertainty factors (UF) used in MRL derivation:

[X] 1 [ ] 3 [ ] 10 (for use of a NOAEL)
[X] 1 [ ] 3 [ ] 10 (for extrapolation from animals to humans)
[ ] 1 [X] 3 [ ] 10 (for human variability/sensitive population)

Was a conversion factor used from nnm in food or water to a me/body weight dose?
If so, explain:

No.

If an inhalation study in animals, list conversion factors used in determining human eauivalent dose:

Not applicable.

Was a conversion used from intermittent to continuous exposure?

No.

Other additional studies or pertinent information that lend sunport to this MRL:

Husen (1959) reported a study involving 269 pairs of Swedish monozygotic (identical) twins where the intrapair IQ difference was 4 IQ points for a combination of twins raised together and apart. This is somewhat lower than the value of 7 IQ points for identical twins raised apart, and just larger than the range of IQ scores for Washington DC children repetitively tested (Jacobi and Glauberman 1995).

Supporting evidence for the acute MRL is provided by Jacobi and Glauberman (1995). Children in the Ist, 3rd, and 5th grades born in Washington DC were tested, and average IQ levels of 94.2,97.6, and 94.6 were reported. The range of 3.4 IQ points is considered to be a LOAEL for this study, which, if used for MRL derivation, would yield an MRL of 0.004 Sv (3.4 IQ points x 1 Sv/25 IQ points ÷ 30 [10 for use of a LOAEL and 3 for a sensitive population]).

Additional supporting evidence for the acute MRL is provided by Berger et al. 1997, in a case study of accidental radiation injury to the hand. A Mexican engineer suffered an accidental injury to the hand while repairing an x ray spectrometer. The day after the accident, his symptoms included a tingling sensation and itching in the index and middle fingers. On days 4 and 7, a “pinching” sensation, swelling, and slight erythema were observed. By day 7, the tip of his index fingers was erythematous and a large blister developed with swelling on other fingers. On day 10, examination by a physician showed that the lesions had worsened and the fingers and palms were discolored. On day 10, he was admitted to the hospital where hyperbaric oxygen therapy was administered without success. One month after the accident, the patient entered the hospital again with pain, discoloration, and desquamation of his hand. Clinical examination showed decreased circulation in the entire hand, most notably in the index and middle finger. Total white blood count decreased to 3,000/µL (normal range 4,300-10,800/µL). Cytogenic studies of peripheral blood lymphocytes revealed four dicentrics, two rings, and eight chromosomal fragments in the 300 metaphases studied. The estimated whole body dose was reported to be 0.382 Gy (38.2 rad). This dose is a potential LOAEL for acute ionizing radiation and would yield an MRL of 0.004 Sv (0.38 Sv ÷100 [10 for use of LOAEL and 10 for sensitive human population]).

The Nuclear Regulatory Commission set a radiation exposure limit of 0.5 rems (50 mSv) for pregnant working women over the full gestational period (USNRC 1991). For the critical gestational period of 8 to 15 weeks ATSDR believes that the conservative acute MRL of 4 mSv is consistent with the NRC limit and could be applied to either acute (0-14 day) or intermediate (15-365 day) exposure periods.

Calculations

Given: 0.3 IQ point is a NOAEL. A 1 Sv dose results in a 25 IQ point reduction (range = 21-29 pts; mean = 25) and provides a conversion factor from IQ prediction to radiation dose. Assume that the radiation dose and the subsequent reduction in IQ is a linear relationship.

MRL=NOAEZL x CF ÷ UF
MRL = 0.3 x 1/25 ÷ 3
MRL = 0.004 Sv = 4 mSv (400 mrem)

Agency Contact (Chemical Manager): Sam Keith.

MINIMAL RISK LEVEL (MRL) WORKSHEET

Chemical name: Ionizing Radiation
CAS number: Multiple
Date: October 1, 1999
Profile status: Final
Route: [ ] Inhalation [ ] Oral [X] External
Duration: [ ] Acute [ ] Intermediate [X] Chronic
Species: Human

MRL: 1 [] mg/kg/day [ ] ppm [ ] mg/m^3 [X] mSv/yr (100 mrem/yr)

Reference: BEIR V. 1990. Health effects of exposure to low levels of ionizing radiation. Committee on the Biological Effects of Ionizing Radiations, National Research Council. National Academy Press. Washington, DC.

Experimental design: Not applicable

Effects noted in study and corresnonding doses:

No individual studies were identified that could be used to base a chronic-duration external exposure MRL that did not result in a cancer-producing end point. However, two sources of information were identified that did provide doses of ionizing radiation that have not been reported to be associated with detrimental effects (NOAELs). These sources provide estimates of background levels of primarily natural sources of ionizing radiation that have not been implicated in producing cancerous or non-cancerous toxicological endpoints. BEIR V states that the average annual effective dose to the U.S. population is 3.6 mSv/yr. A total annual effective dose equivalent of 3.6 mSv (360 mrem)/year to members of the U.S. population is obtained mainly by naturally occuring radiation from external sources, medical uses of radiation, and radiation from consumer products. The largest contribution (82%) is from natural sources, two-thirds of which if from naturally occurring radon and its decay products. Specific sources' of this radiation are demonstrated in Table A- 1.

The annual dose of 3.6 mSv per year has not been associated with adverse health effects or increases in the incidences of any type of cancers in humans or other animals.

Dose endpoint used for MRL derivation: 3.6 rnSv/yr

[X] NOAEL [ ] LOAEL 3.6 mSv/yr

Uncertainty factors (UF) used in MRL derivation:

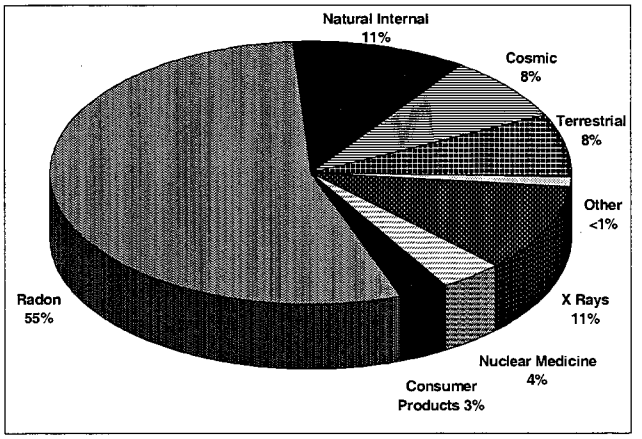
[X] 1 [ ] 3 [ ] 10 (for use of a NOAEL)
[X] 1 1] 3 [ ] 10 (for extrapolation from animals to humans)
[ ] 1 [X] 3 [ ] 10 (for human variability)

Was a conversion factor used from ppm in food or water to a mg/bodv weight dose?
If so, explain: No.

APPENDIX A

Table A-1. Average Annual Effective Dose Equivalent of Ionizing Radiation to a Member of the U.S. Population[a]

Source	Effective Dose Equivalent	
	mSv	Percent of Total Dose
Natural		
Radon[b]	2.0	55
Cosmic	0.27	8.0
Terrestrial	0.28	8.0
Internal	0.39	11
Total Natural	3.0	82
Artificial		
Medical		
X-ray	0.39	11
Nuclear	0.14	4.0
Consumer Products	0.10	3.0
Other		
Occupational	<0.01	<0.3
Nuclear Fuel Cycle	<0.01	<0.03
Fallout	<0.01	<0.03
Miscellaneous[c]	<0.01	<0.03
Total Artificial	0.63	18
Total Natural and Artificial	3.6	100



[a] adapted from BEIR V, Table 1-3 , page 18.
[b] Dose equivalent to bronci from radon daughter products
[c] DOE facilities, smelter, transportation, etc.

If an inhalation study in animals, list conversion factors used in determining human equivalent dose:

Not applicable.

Was a conversion used from intermittent to continuous exposure?

No.

Other additional studies or pertinent information that lend support to this MRL:

ICRP has developed recommended dose limits for occupational and public exposure to ionizing radiation sources. The ICRP recommends limiting public exposure to 1 mSv/yr (100 mrem/yr), but does note that values at high altititues above sea level and in some geological areas can sometimes be twice that value (≥2 mSv). In Annex C of ICRP 60, the commission provides data that suggests increasing the dose from 1 mSv to 5 mSv results in a very small, but detectable, increase in age-specific human mortality rate. ICRP states that the value of 1 mSv/yr was chosen over the 5 mSv value because 5 mSv/yr (500 mremlyr) causes this increase in age specific mortality rate, and 1 mSv/yr (100 rnrem/yr) is typical of the annual effective dose from background, less radon (ICRP 1991). The 1 mSv estimate may underestimate the annual exposure to external sources of ionizing radiation to the U.S. population, as it does not include radiation from radon. Conversely, the 5 mSv estimate may be high, in that increases in mortality rate been reported. The most useful estimate appears to be the BEIR V estimate of 3.6 mSv, in that it accounts for an annual exposure to radon, is specific to the U.S. population, has not been associated with increases mortality, and it falls short of the 5 mSv value associated with small increases in human mortality.

Calculations

$MRL = NOAEL_{(ADJ)} \div Uf$
MRL = 3.6 mSv/yr ÷ 3
MRL = 1.20 mSv/yr
MRL = 1.0 mSv/yr = 100 mrem/yr above background

Agency Contact (Chemical Manager): Sam Keith.

APPENDIX B

USER'S GUIDE

Chapter 1. Public Health Statement

This chapter of the profile is a health effects summary written in non-technical language. Its intended audience is the general public, especially people living in the vicinity of a hazardous waste site or chemical release. If the Public Health Statement were separate from the rest of the document, it would still communicate to the lay public essential information about the chemical.

The major headings in the Public Health Statement are useful for finding specific topics of concern. The topics are written in a question and answer format. The answer to each question includes a sentence that direct the reader to chapters in the profile that provide more information on the given topic.

Chapter 2. Principles of Ionizing Radiation

This chapter is an introductory discussion of the principles of ionizing radiation. It addresses what ionizing radiation is and provides a brief overview of the history of ionizing radiation as it pertains to health effects and uses, both peaceful and military. The chapter goes on to discuss the concept of radioactive transformation and the concept of half-life, characteristics of nuclear radiation, how radiation interacts with matter, ionizing radiation and DNA interactions, energy deposition in biological tissues, radiation dosimetry, and internal vs. external exposure. Chapter 2 also introduces the concept of dose-response and the concept of acute and chronic (delayed) health effects, in addition to briefly summarizing the major health effects caused by exposure to ionizing radiation. This chapter concludes with a thorough discussion of how ionizing radiationis measured, internally, externally, and in media using a variety of instruments.

Chapter 3. Summary of Health Effects of Ionizing Radiation

This chapter provides an overview of the health effects related to ionizing radiation exposure in humans and laboratory animals. The top 25 radionuclides present currently or in the past at Department of Energy (DOE) waste sites are identified and some information on their physical half-life and retention characteristics in the body are summarized. The health effects associated with exposure to ionizing radiation are summarized and divided into non-carcinogenic and carcinogenic responses for discussion purposes. A discussion of the non-carcinogenic health effects by major organ system iss presented, followed by a discussion of the carcinogenic responses using data from laboratory animals and the limited amount of human data available. The effects of ionizing radiation on teratogenesis, reproduction, genotoxicity, and ocular toxicities, including the available information on human risk assessments, are also addressed. Readers are encouraged to use Chapter 8 as a supplement to the discussion of the health effects presented in Chapter 3 of this profile.

Chapter 4. Radiation Accidents

This chapter discusses the major radiation accidents of this century, including health effects data, if such data were reported.

Chapter 5. Mechanisms of Biological Effects

This chapter discusses the major mechanisms by which ionizing radiation exerts it toxic effects on cellular activities and organ systems. This discussion addresses the major target molecules of ionizing radiation, with emphasis on how ionizing radiation interacts with DNA. The concept of direct vs. indirect damage to DNA and other macromolecules is also introduced, followed by a discussion of how these mechanisms induce specific types of damage to macromolecules, cells, tissues, and organs to elicit a toxic or adverse event. A brief discussion of the mechanisms by which ionizing radiation induces cancer in laboratory animals and humans is presented, along with a number of models that reflect possible mechanisms of cancer induction and a brief discussion of the three steps of cancer formation.

Chapter 6. Sources of Population Exposure to Ionizing Radiation

There are many ways humans and animals can be exposed to ionizing radiation. This chapter addresses the potential for exposure to sources of ionizing radiation to the human population. Exposure to ionizing radiation is divided into natural external (cosmic rays, terrestrial, coal production, crude oil and natural gas, hot springs and caves, etc.), anthropogenic external (nuclear weapons, fallout, nuclear fuel cycle, medical, dental, and occupational) and internal exposure (inhalation, oral and dermal routes). Discussion of the human health hazards associated with each type of exposure is also presented in this chapter.

Chapter 7. Regulations

This chapter provides summarizes the regulations pertaining to radionuclides.

Chapter 8. Levels of Significant Exposure to Radiation and Radioactive Material

Tables 8-1 (inhalation exposure), 8-2 (oral exposure), 8-3 (dermal exposure), and 8-4 (external exposure) are used to summarize health effects associated with exposure to ionizing radiation. These tables cover the health effects observed at increasing radiation doses and durations, the specific isotope and activity used, and the differences in response by species. These tables provide a quick review of the health effects and a convenient way to locate data for a specific exposure scenario. The tables should be used in conjunction with the text in chapters 2, 3 and 4. All entries in these tables represent studies that provide reliable, quantitative estimates of no-observed-adverse-effect levels (NOAELs), lowest-observed-adverse-effect levels (LOAELs), or cancer effect levels (CELs).

Chapter 9. Glossary

This chapter contains of definitions and terminology pertaining to ionizing radiation and should be consulted when reviewing and interpreting the data present in chapters 2 through 8 of this toxicological profile.

Chapter 10. References

This chapter lists the references used to construct this profile and references that the reader may use to obtain more information on many of the topics discussed in this profile.

APPENDIX C

ACRONYMS, ABBREVIATIONS, AND SYMBOLS

AMAD	Activity Median Aerodynamic Diameter
ATSDR	Agency for Toxic Substances and Disease Registry
Bq	becquerel
C	Centigrade
CDC	Centers for Disease Control
CEL	Cancer Effect Level
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
Ci	curie
cm	centimeter
CNS	central nervous system
d	day
DHHS	Department of Health and Human Services
DOD	Department of Defense
DOE	Department of Energy
DOT	Department of Transportation
ECG	electrocardiogram
ED_{50}	Effective Dose 50%
EEG	electroencephalogram
EPA	Environmental Protection Agency
EKG	see ECG
ERAMS	Environmental Radiation Ambient Monitoring System
ERD	Environmental Radiation Data
F	Fahrenheit
F_1	first filial generation
ft	foot
g	gram
Gy	gray
HPS	Health Physics Society
hr	hour
IAEA	International Atomic Energy Agency
IARC	International Agency for Research on Cancer
ICRP	International Commission on Radiological Protection
ILB	Initial Lung Burden
IPB	Initial Pulmonary Burden
in	inch
J	joule
kg	kilogram
L	liter
LC_{50}	lethal concentration, 50% kill
LD_{Lo}	lethal dose, low
LD_{50}	lethal dose, 50% kill
$LD_{50/30}$	Lethal Dose 50%/30 days
LOAEL	lowest-observed-adverse-effect level
mg	milligram

min	minute
mL	milliliter
mm	millimeter
MRL	Minimal Risk Level
NAREL	National Air and Radiation Environmental Laboratory
NCRP	National Council on Radiation Protection and Measurements
NRC	Nuclear Regulatory Commission
ng	nanogram
nm	nanometer
NPL	National Priorities List
NRC	Nuclear Regulatory Commission
NTIS	National Technical Information Service
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PHS	Public Health Service
ppm	parts per million
R	roentgen
sec	second
SCE	sister chromatid exchange
SMR	standard mortality ratio
STEL	short term exposure limit
STORET	STORAGE and RETRIEVAL
STP	standard temperature and pressure
Sv	sievert
TWA	time-weighted average
U.S.	United States
yr	year
wk	week

>	greater than
≥	greater than or equal to
=	equal to
<	less than
≤	less than or equal to
%	percent

Greek letters

α	alpha
β	beta
γ	gamma
μ	micro

APPENDIX C

Prefixes for radiological and physical units

a	atto	10^{-18}
c	centi	10^{-2}
d	deci	10^{-1}
E	exa	10^{18}
f	femto	10^{-15}
G	giga	10^{9}
k	kilo	10^{3}
p	pico	10^{-12}
m	milli	10^{-3}
M	mega	10^{6}
n	nano	10^{-9}
P	peta	10^{15}
T	tera	10^{12}
µ	micro	10^{-6}

Radiation units

Bq	becquerel
Ci	Curie
Gy	Gray
R	roengten
Sv	Seivert

APPENDIX D

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