A REVIEW OF THE QUANTITIES AND MODELS USED IN INTERNAL DOSE CALCULATIONS

S. Sherbini
US Nuclear Regulatory Commission

ABSTRACT

Activities in which unsealed radioactive materials are present or are handled may involve intakes into the body of these materials by workers or by members of the public. Intake routes may be by inhalation of contaminated air or ingestion of contaminated food or drink. Less common routes of intake are entry into the body through a wound or through intact skin. To assess the health impacts of such intakes, it is necessary to calculate the resultant doses to the various organs and tissues of the body. These calculations require the use of mathematical equations, called biokinetic models, that describe the behavior of the radioactive material from its entry into the body until its removal by decay or by excretion, or its long-term retention in the body. This paper describes some aspects of these models, their evolution over the past 30 years, the associated dosimetric quantities, and their application in regulating the use and disposal of radioactive materials. The impact of the revisions that the models and dosimetric quantities have undergone is also discussed.

QUANTITIES USED IN DOSE ASSESSMENT

Absorbed Dose

The basic dosimetric quantity in radiation protection is the absorbed dose, defined as the energy absorbed per unit mass of material, and usually represented by the letter D. For assessing doses to organs or tissues, the dose is normally the average dose over the entire organ or tissue. The currently recommended unit for absorbed dose is joules per kilogram, with the special unit of gray (Gy), equal to 1 J/Kg. The older and still widely used unit of dose is ergs/gm, with the special unit of rad, equal to 100 ergs/gm, or 0.01 J/Kg, giving the relationship of 100 rad per Gy.

Restricting this discussion to biological effects, the absorbed dose is a satisfactory dosimetric quantity only if one is assessing the impact of one type of radiation of a single energy. However, different types of radiation, or the same type of radiation but with different energies, deposit their energies in tissue in different spacial patterns and at different rates. For example, a 1 MeV photon will deposit its energy at the rate of about 100 keV per micrometer (μm) of track, whereas a heavy charged particle may deposit energy at the rate of up to 2000 keV per μm or higher. The rate of energy deposition or loss by radiation is called the stopping power, S, or the linear energy transfer, LET. Low-LET radiations produce sparsely distributed ionizations along their tracks, whereas high-LET radiations produce densely packed ionizations. The density of ionizations has a significant impact on the biological effect of the radiation, with the result that a dose of 1 rad will have a different biological impact depending on the type and energy of the radiation that produced that dose, that is, on the LET of the radiation. For assessing health effects, therefore, the dose in rads by itself is not a satisfactory quantity. Note also that doses in rads produced by different types of radiation with very different LETs are generally not additive when assessing health effects or risk. That is, a dose in rads produced by photons cannot be directly added to a dose in rads produced at the same location by, say, neutrons, without first making allowances for the differences in effectiveness of the two types of radiation in producing the health effect under consideration.

Dose Equivalent/Equivalent Dose

To produce a more uniform scale of biological impact by different types of radiation, and also to permit the addition of doses deposited by different types and energies of radiation in order to obtain the total dose that is indicative of risk, the absorbed dose caused by each type of radiation is multiplied by a normalizing factor that takes into account the relative effectiveness of the radiation in producing the biological effect in question. In radiation protection, the effect of concern is normally radiogenic cancer and hereditary effects, known as stochastic effects. The product of the absorbed dose and this modifying factor is called the dose equivalent (ICRP, 1977), H_E or, in the more recently recommended terminology (ICRP, 1990), the equivalent dose. The modifying factor used to obtain the dose equivalent is called the quality factor, Q, and the factor used to calculate the equivalent dose is called the radiation weighting factor, w_R. NRC regulations and guidance currently use the quality factor Q to calculate the dose equivalent (NRC, 2003). Q is a function of the LET, but w_R is specified in terms of the type and energy of the incident radiation. The recommended values of Q and w_R are shown in Table (1) below.

Table I Values of Q and w_R for different radiation types

TYPE OF RADIATION	Q	W_R
Photons, all energies	1	1
Electrons, all energies	1	1
Alpha Particles, fission fragments	20	20
Neutrons <10 keV		5
10 - 100 keV		10
100 keV - 2 MeV		20
2 MeV - 20 MeV		10
> 20 MeV		5
Neutrons, protons, particles of single charge and mass > 1 amu of unknown energy	10	

As Table I indicates, there has been little change in numerical values when using w_R in place of Q for most radiations of interest in waste management activities. However, there is a significant conceptual difference between these two quantities. The Q value is intended to be applied at the point in the absorbing medium at which the radiation deposits its energy, whereas w_R is to be applied to the radiation incident on the body. This has no impact when dealing with photons and electrons, because Q and w_R are always 1. However, neutrons slow down as they penetrate into the body, i.e. their energies decrease, and therefore the Q value changes with depth of penetration, whereas w_R remains constant because it is determined only by the incident neutron field. In addition, neutrons penetrating into the body produce secondary gamma radiation. This gamma component may become the dominant contributor to dose toward the exit side of the body, and Q for this radiation is 1. The result is that neutron equivalent dose, which is calculated using w_R, is, for certain incident neutron energies, greater than the dose equivalent by a factor of up to about 2. For photon and electron irradiations, there is no numerical difference between the dose equivalent and the equivalent dose. The unit of equivalent dose is 1 J/kg, with the special name sievert (Sv). The older and still widely used unit is ergs/gm, with the special unit of rem, equal to a dose of 1 rad modified by the Q value.

The dose equivalent, using Q as the weighting factor, is still recommended for use in international recommendations such as those by ICRP, but only in calculating what are called the operational quantities. These quantities are meant to be measured in the field and are intended to provide estimates for the protection quantities (the protection quantities are the organ and tissue equivalent doses and the effective dose), which are usually difficult or impossible to measure in the field. The currently recommended operational quantities are the ambient dose equivalent, $H^*(d)$, directional dose equivalent, $H(\Omega,d)$, and personal dose equivalent, $H_P(d)$ (ICRU,1980,1993). Survey instruments, area monitors, and personnel dosimetry are intended to be calibrated to measure one of these operational quantities. It should be noted in this context that the Roentgen, R, which is a unit of exposure that has been widely used in the past and is still in common use, has been discontinued and replaced by the kerma, and survey instruments formerly calibrated to measure exposure in terms of R will instead be calibrated to measure kerma in units of Gy.

Effective Dose Equivalent /Effective Dose

Prior to 1977, radiation protection was based on the concept of the critical organ, which was defined as the organ whose radiation exposure posed the greatest risk to the exposed person. This was normally the organ that received the highest dose, and the dose to the critical organ was used to control radiation exposure (ICRP, 1959). Starting in 1977, use of the critical organ concept was discontinued, and a new quantity was introduced, called the effective dose equivalent (ICRP, 1977). This was defined as the sum of the doses to a defined set of organs thought to be most susceptible to radiation-induced cancer, with each organ dose weighted by a factor that is proportional to the relative contribution of that organ or tissue to the overall stochastic detriment (which includes cancer mortality, cancer morbidity, years of loss of life, and hereditary effects) when the body is subjected to uniform whole body radiation exposure.

$$H_E = \Sigma H_T w_T \qquad \text{(Eq. 1)}$$

where, H_T = average dose equivalent in tissue or organ T
w_T = tissue weighting factor for tissue or organ T

The unit of H_E is the same as that for dose equivalent, namely rem or Sv. In 1990, the tissue weighting factors were revised, both by including more organs in the list and also by changing the values for the organs previously included in the definition of effective dose equivalent (ICRP, 1990). The quantity calculated using the revised tissue weighting factors is called the effective dose, E. Table (2) shows the weighting factors used to calculate the effective dose equivalent and the effective dose. It should be noted that the effective dose equivalent contained as part of its definition the specific set of weighting factors listed in ICRP Publication-26, whereas the effective dose is defined independently of any specific set of tissue weighting factors used for its calculation, such as those listed in ICRP Publication-60. From that perspective, the effective dose equivalent may be viewed as a special case of the effective dose. The NRC still uses the effective dose equivalent in its regulations and guidance.

The effect of changing from effective dose equivalent, H_E to effective dose E, is relatively small for situations involving external photon exposures. For such cases, H_E is slightly higher than E above 20 keV, by a maximum of about 12% at 100 keV, and less than that at other energies. Below 20 keV, E may exceed H_E in some irradiation geometries, primarily because of the inclusion of skin in the calculation of E but not H_E . For neutrons between thermal and 1 MeV, E is higher than H_E by a factor of 2 - 4 for radiation incident from the front of the body, primarily because of the use of w_R in place of Q. This ratio may be much higher for other irradiation geometries. E and H_E tend to become equal for all geometries as the neutron energies increase, and approach 1 by 10 MeV. For electrons, E is about 0.7 of H_E between 1

Table II Tissue weighting factors for calculating effective dose equivalent and effective dose.

TISSUE OR ORGAN	EFFECTIVE DOSE EQUIVALENT, H_E	EFFECTIVE DOSE, E
Gonads	0.25	0.20
Red Bone Marrow	0.12	0.12
Colon	-	0.12
Lung	0.12	0.12
Stomach	-	0.12
Bladder	-	0.05
Breast	0.15	0.05
Liver	-	0.05
Esophagus	-	0.05
Thyroid	0.03	0.05
Skin	-	0.01
Bone Surface	0.03	0.01
Remainder	0.30	0.05

and 10 MeV, but E becomes increasingly higher below 1 MeV, and may exceed H_E by a factor of about 3 at 0.5 MeV, and more at lower energies, primarily because of the inclusion of skin in its calculation.

The effects of changing from H_E to E are more complex for internal dosimetry, and must be considered separately for each radionuclide. In some cases, E is much lower than H_E but in others it is higher. These will be discussed in a separate section of this paper.

Committed Effective Dose Equivalent

Internally deposited radionuclides deliver dose to organs over a period of time that may last up to the lifetime of the exposed individual, and the doses delivered from one year to the next are usually not equal. One approach to assessing the impact of these radionuclides is to calculate the dose for each year following intake, and add that to any external dose for that year to arrive at the total dose for the year. This approach, however, was tried and has been found to be logistically very difficult to implement. The year-by-year approach is especially challenging when estimating doses to members of the public. Therefore, the nearly universal practice now is to calculate the total dose that would be delivered to the organ from the time of intake up to 50 years following the intake for workers, and up to age 70 for members of the public, and to assign that dose to the year in which the intake occurred. A more important reason for adopting this method of control of exposure is that it achieves the primary protection purpose of limiting the lifetime risk committed in a year of practice, and not the risk incurred in one year as a result of an intake. The integrated dose is called the committed dose equivalent or the committed equivalent dose, depending on whether Q or w_R is used in the calculations, respectively. As with external dose, the weighted tissue and organ doses are added to calculate

the committed effective dose equivalent or the committed effective dose. Finally, adding the external and internal dose components yields the total effective dose equivalent or the total effective dose.

Dose Commitment

Long-lived radionuclides released by a practice will often tend to remain in the environment for long-periods of time after the release has occurred, and will therefore continue to expose members of the public. For a continuing practice, the annual releases will add to previously released activity in the environment and cause a buildup and an increase in exposure levels over time. This will continue until either the buildup levels off when a state of equilibrium is achieved, or the practice ceases operation. The maximum annual dose to individuals that results from this build-up is called the dose commitment from a year of operation, and it is this maximum annual dose that should be limited.

Collective Dose

Another quantity that has found wide application is the collective dose, which is the sum of all doses received by all members of a specified exposed population, such as all members of the public exposed to radiation and radioactive materials from a decommissioning project. The concept of collective dose has been used extensively in optimization, or ALARA (As Low As is Reasonably Achievable) assessments, and is one of the useful means available to compare the total radiation risk resulting from different ways of completing a project, or to compare different options for achieving a specified goal. Although the use of the collective dose to predict the number of latent cancer fatalities from a proposed action is controversial, this quantity continues to be very useful and is used widely.

BIOKINETIC MODELS FOR INTERNAL DOSE ASSESSMENT

Internal dose is the dose to organs and tissues of the body that results from entry of radioactive material into the body. Routes of entry for occupationally exposed workers are normally confined to inhalation of air containing radioactive aerosols or gases. This is the case because it is usually possible to restrict eating and drinking in contaminated areas of the workplace. For members of the public, routes of entry will normally include ingestion of radioactive material in the form of contaminated food and drink as well as inhalation of contaminated air, and less frequently by entry through wounds or through intact skin.

Internal dose cannot be measured directly, and must therefore be calculated using mathematical models that describe the behavior of radioactive material once it enters the body. These models are known as biokinetic models because they describe the time behavior of the radioactive material in a biological system, the human body. Traditionally, biokinetic models have been developed as a set of independent components, each dealing with one aspect of the biokinetic behavior of the material. Inhalation of material is analyzed using a lung model, which describes the deposition of material in different parts of the respiratory tract and its clearance from the respiratory tract by absorption into body fluids or by swallowing. Passage of material through the gastrointestinal tract (GI) and its absorption during its passage is described by a GI tract model. The behavior of material that is absorbed into body fluids is described by a set of systemic biokinetic models, usually a different model for each element of importance. These models describe the deposition of the radioactive material in the various organs and tissues, and clearance of the materials from the body and their excretion in urine, or in some cases in feces. In some situations, separate excretion models are also used to describe the rate of excretion of radioactive materials.

The GI, Lung, and systemic models underlying most current NRC regulations, including 10 CFR Part 20, are described in International Commission on Radiological Protection (ICRP) Publications 26 (ICRP, 1977) and 30 (ICRP,1978). ICRP-30 also provides a series of systemic models for many elements of importance in the

use of radioactive materials. These models have undergone a series of modifications, and in many cases extensive revisions, over the past 15 years or so, staring with ICRP Publication 56 (ICRP, 1989). In that publication, ICRP introduced age-specific systemic models for 12 elements: hydrogen (H), carbon (C), strontium (Sr), zirconium (Zr), niobium (Nb), Ruthenium (Ru), iodine (I), cesium (Cs), cerium (Ce), plutonium (Pu), americium (Am), and neptunium (Np). Dose coefficients tabulated in this publication were calculated using these new systemic models together with the weighting factors in ICRP-26 and the lung and GI models in ICRP-30. The ages considered, and the age ranges to which each age is applicable, were: 3 months (0 - 12 months), 1 year (1 - 2 years), 5 years (2 - 7 years), 10 years (7 - 12 years), 15 years (12 - 17 years), and adult (more than 17 years).

The next major revision came with publication of a new human respiratory tract model (HRTM) in ICRP Publication 66 (ICRP, 1994a). This model introduced a series of important developments, including identification of the tissues at risk in each section of the respiratory tract (rather than considering the lung as a whole, as in the older model), improved deposition and clearance models, and the ability to consider different age groups. The model also applies to a wider range of aerosol sizes as well as to gases and vapors. Clearance from the lungs, which in ICRP-30 was considered a single process, is separated in the new model into two components: transport and absorption. This permits more closely matching the known solubility characteristics of specific compounds to the parameters in the lung model.

Additional age-dependent systemic models were introduced in ICRP Publication 67 (ICRP, 1993) for sulphur (S), cobalt (C), nickel (Ni), zinc (Zn), molybdenum (Mo), technetium (Tc), silver (Ag), tellurium (Te), barium (Ba), lead (Pb), polonium (Po), and radium (Ra). Previously introduced models for Sr, Pu, Am, and Np were also updated using recently developed data. ICRP Publication 69 (ICRP, 1995a) added 5 more elements to the list of age-specific systemic models: iron (Fe), antimony (Sb), selenium (Se), thorium (Th), and uranium (U), bringing the total number of elements for which age-specific systemic biokinetic models were developed to 31. Systemic age-dependent models for the remaining elements were adapted from those described in ICRP-30 by making allowance for several factors: age-specific differences in absorption of activity from the GI; age-specific differences in body and organ masses as well as differences in the relative positions, or geometry, of the organs; and age-specific differences in excretion rates. The systemic biokinetics in these adapted models remained the same as those for adults. In addition, unlike the usual method of treating daughter products produced in the body by using the same models as those for the parents, the daughter products of Pb, Ra, Te, Th, and U produced in the body were analyzed using different systemic models from those used for the parents.

Dose coefficients calculated using all of the revised models are tabulated for workers in ICRP Publication 68 (ICRP, 1994b), and age-specific effective doses are tabulated in ICRP 72 (ICRP 1996) for members of the public. In addition, a CD ROM published by the ICRP (ICRP, 1999) contains the databases used to generate the doses tabulated in ICRP-68 and ICRP-72. This database contains the equivalent doses to the individual organs and tissues used in calculating the effective doses. Dose coefficients based on the ICRP-30 models are tabulated in several references, included the Environmental Protection Agency's (EPA) Federal Guidance Report #11 (EPA, 1988) for internal doses, and EPA's Federal Guidance Report #12 for external doses (EPA, 1993). These coefficient are not age-dependent. EPA has also developed a set of age-dependent dose and risk coefficients for members of the public using the revised ICRP biokinetic models, but these coefficients differ from those published ICRP-72 in that they are weighted average coefficients, weighting being by age and gender distributions reflective of the US population, and using cancer mortality data obtained from data on US cancer mortality (EPA, 1999).

All of the biokinetic models are time-dependent, that is, they describe the behavior of the materials as a function of time following intake. This is important because the dose to an organ or tissue depends on the length of time the material irradiates this organ or tissue. The end result of application of the biokinetic

models is a set of functions that describe the activity of radioactive material in each organ and tissue as a function of time, starting from the time of intake until the material is excreted or until the end of the integration period. The models are all linked in that the results from one set of models, say the lung of GI models, provides input to the next set of models, and so on. They are therefore solved as a set of interlinked equations.

The solutions of the biokinetic models form the input to the dosimetric models, which are models that are used to calculate the total dose over a specified time period to each organ and tissue in the body as a result of the activities present in all the organs and tissues of the body during that time period. These doses are the committed organ dose equivalents or equivalent doses, which are then used to calculate the effective dose equivalents or effective doses.

IMPACT OF THE REVISED MODELS

As indicated above, the revisions introduced by the ICRP since 1977 included a redefinition of basic radiation protection quantities, introduction of the radiation weighting factor, adoption of a revised set of tissue weighting factors, a new lung model, and a revised set of age-dependent biokinetic models for many important radionuclides. The effect of all of these changes is complex and radio-nuclide dependent. It has been minimal for many radionuclides, but has increased the estimated dose per unit intake for some, and reduced the dose per unit intake substantially for others. Much of the data on the impacts of these changes was obtained from an Oak Ridge National Laboratory Study prepared by R.W. Leggett and K.F. Eckerman (Leggett, 2003). The ratios of E/H_E for inhalation and ingestion of some of the radionuclides that changed substantially, for workers and for members of the public, are shown in the Table III below.

Table III Ratios of the effective dose to the effective dose equivalent for a selection of radionuclides that were most affected by the revisions of the ICRP quantities and biokinetic models.

MODE OF INTAKE	CLEARANCE TYPE	E/H_E
INHALATION - OCCUPATIONAL		
Th-226, Bi-212, Bi-213, Bi-214	M	8 - 13
Th-229, Np-237, Ac-227	M	0.1 - 0.12
Ac-227, Th-229, Th-230, Th-232, U-233, U-234, U-235, U-238, Pu-238, Pu-239, Pu-240, Pu-241	S	0.06 - 0.12
INGESTION - OCCUPATIONAL		
Np-237, Pu-238, Pu-239, Pu-240, Pu-241, Pu-242, Am-241		0.08 - 0.33
INHALATION - PUBLIC		
Sr-90, Cs-137 (infants, children)	F	0.1 - 0.2
Ac-227, Th-229, Np-237n (all ages)	M	0.02 - 0.2
Ac-227, Th-229, Th-230, Th-232, Pu-239, Pu-240, Pu-241, Cf-251 (all ages)	S	0.03 - 0.2
Bi-212, Bi-214, Th-226 (all ages)	M	5 - 10
INGESTION - PUBLIC		
Fe-55, Fe-59, Fe-60 (pre-adult)		3 - 5
Most iodine radionuclides (infants, children)		3 - 4
Cs-134, Cs-137 (infants)		0.2 - 0.3
Po-210 (all ages)		3 - 9
Ac-227, Th-232, Np-237, Pu-238, Pu-239, Pu-240, Pu-241, Am-241 (over 1 year)		0.04 - 0.3

The absorption Types F, M, and S refer to the rates at which material is absorbed from the respiratory tract to body fluids, and stand for fast, medium, and slow, respectively. They correspond roughly to the classification system currently used in NRC's regulations and guidance, namely clearance Classes D, W, and Y for days, weeks, and years, respectively.

REGULATORY POSITION

NRC has not formally adopted ICRP's revised models and quantities. NRC's regulations and guidance are therefore still based on the quantities and models recommended by ICRP in its ICRP-26 and ICRP-30 publications, and licensees are expected to use these models, or tabulations produced from these models, in showing compliance with regulatory and license requirements. NRC has, however, approved the use of the revised quantities and models, both in occupational as well as environmental applications, on a case-by-case basis in response to licensee requests. The approvals require that, if the licensee is to adopt the revised models, then all of the licensee's operations must be based on these revised models. In other words, the models cannot be selectively applied to certain radionuclides or intake pathways and not to others within the licensee's operations.

REFERENCES

1 R.W. Leggett and K.F.Eckerman, Dosimetric Significance of the ICRP's Updated Guidance and Models, 1989-2003, and Implications for U.S. Federal Guidance, Oak Ridge National Laboratory, ORNL/TM-2003/207, August 2003.

2 EPA, 1988, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," US Environmental Protection Agency, EPA-5201/1-88-020, Washington DC, 1988.

3 EPA, 1993, "External Exposure to Radionuclides in Air, Water, and Soil," US EPA-402-R-93-081, Washington DC, 1993.

4 EPA, 1999, "Cancer Risk Coefficients for Environmental Exposure to radionuclides," US EPA 402-R-99-001, Washington DC, 1999.

5 ICRP, 1959, "Recommendations of the International Commission on Radiological Protection," ICRP Publication 1, Pergamon Press, New York, 1959.

6 ICRP, 1977, "Recommendations of the International Commission on Radiological Protection," ICRP Publication 26, Pergamon Press, New York, 1977.

7 ICRP, 1978, "Limits of Intakes of Radionuclides by Workers," ICRP Publication 30, Pergamon Press, New York, 1978.

8 ICRP, 1989, ""Age-Dependent Dose to Members of the Public From Intake of Radionuclides: Part1," ICRP Publication 56, Annals of the ICRP 20(2), Pergamon Press, New York, 1989.

9 ICRP, 1990, "1990 Recommendations of the International Commission on Radiological Protection," ICRP Publication 60, Pergamon Press, New York, 1990.

10 ICRP, 1993, "Age-Dependent Dose to Members of the Public from Intake of Radionuclides: Part 2, Ingestion Dose Coefficients," ICRP Publication 67, Annals of the ICRP 23 (3-4), Pergamon Press, New York, 1993.

11 ICRP, 1994a, "Human Respiratory Tract Model for Radiological Protection," ICRP Publication 66, Annals of the ICRP 24(1-3), Pergamon Press, New York, 1994.

12 ICRP, 1994b, ""Dose Coefficients for Intakes of Radionuclides by Workers," ICRP Publication 68, Annals of the ICRP 24(4), Pergamon Press, New York, 1994.

13 ICRP, 1995a, "Age-Dependent Dose to Members of the Public From Intake of Radionuclides: Part 3, Ingestion Dose Coefficients," ICRP Publication 69, Annals of the ICRP 25(1), Pergamon Press, New York, 1995.

14 ICRP, 1995b, "Age-Dependent Dose to Members of the Public From Intake of Radionuclides: Part 4, Inhalation Coefficients," ICRP Publication 71, Annals of the ICRP 25(3-4), Pergamon Press, New York,1995.

15 ICRP, 1996, "Age-dependent Dose to Members of the Public From Intake of Radionuclides: Parts 5, Compilation of Ingestion and Inhalation Dose Coefficients," ICRP Publication 72, Annals of the ICRP Publication 72, Annals of the ICRP 26(1), Pergamon Press, New York, 1996.

16 ICRU, 1980, "Radiation Quantities and Units," ICRU Publication 33, 7910 Woodmont Avenue, Bethesda, MD 20814, 1980.

17 ICRU, 1993, "Quantities and Units in Radiation Protection Dosimetry," ICRU Publication 51, 7910 Woodmont Avenue, Bethesda, MD 20814, 1993.

18 ICRP, 1999, "The ICRP Database of Dose Coefficients: Workers and Members of the Public," ICRP CD ROM, Version 1.0, ISBN 0 08 042 7510. CD ROM distributed by Elsevier Science Ltd., Oxford, Ney York, NY, 1999.

19 NRC, 2003, "Standards for Protection Against Radiation," Code Of Federal Regulations, Title 10, Part 20, Office of the Federal Register, Washington D.C., 2003.