by summing the contribution (product of intensity and time) to dose at each step. The dose calculated from the radiation field does not reflect the shielding of the film badge afforded by the human body. This shielding has been determined for pertinent body positions by the solution of radiation transport equations as applied to a radiation field. Conversion factors are used to arrive at a calculated film badge dose, which not only facilitates comparison with film badge data, but serves as a substitute for an unavailable film badge reading.

(3) The calculation of the dose from inhaled or ingested radioactivity primarily involves the determination of what radiosotopes entered the body in what quantity. Published conversion factors are then applied to these data to arrive at the radiation dose and future dose commitments to internal organs. Inhalation or ingestion of radioactive material is calculated from the radioactive environment and the processes of making these materials inhalable or ingestible. Activities and processes that cause material to become airborne (such as wind, decontamination or traffic) are used with empirical data on particle lofting to determine airborne concentrations under specific circumstances. Volumetric breathing rates and durations of exposure are used to calculate the total material intake. Data on time-dependent weapon debris isotopic composition and the above-mentioned conversion factors are used to calculate the dose commitment to the body and to specific body organs.

(e) *Uncertainty analysis.* Because of the uncertainties associated with the radiological data or calculations used in the absence of data, as well as the uncertainties with respect to personnel activities, confidence limits are determined where possible for group dose calculations. The uncertainty analysis quantifies the errors in available data or in the model used in the absence of data. Confidence limits are based on the uncertainty of all relevant input parameters, and thus vary with the quality of the input data. They also consider the possible range of doses due to the size of the exposure group being examined. Typical sources of error include orientation of the weapons, specific weapon yields, instrument error, fallout intensity data, time(s) at which data were obtained, fallout decay rate, route of personnel movements, and arrival/stay times for specific activities.

(f) *Comparison with film badge records.* (1) Calculations of gamma dose were compared with film badge records for two military units at Operation PLUMBBOB to initially validate this methodology. Where all parameters relating to radiation exposure were identified, direct comparison of gamma dose calculations with actual film badge readings was possible. Resultant correlations provided high confidence in the methodology.

(2) Film badge data may, in some cases, be unrepresentative of the total exposure of a given individual or group; nevertheless, they are extremely useful for direct comparison of incremental doses for specific periods, e.g., validating the calculations for the remaining, unbadged period of exposure. Moreover, a wide distribution of film badge data often leads to more definitive personnel grouping for dose calculations and to further investigation of the reason(s) for such distribution. In all cases, personnel film badge data are not used in the dose calculations, but rather are used solely for comparison with and validation of the calculations. For dose reconstructions accomplished to date, comparison has been favorable and within the confidence limits of the calculations.

### §218.4 Dose estimate reporting standards.

The following minimum standards for reporting dose estimates shall be uniformly applied by the Military Services when preparing information in response to an inquiry by the Veterans Administration, in connection with a claim for compensation, or by a veteran or his or her representative. The information shall include all material aspects of the radiation environment to which the veteran was exposed and shall include inhaled, ingested, and neutron doses, when applicable. In determining the veteran's dose, initial neutron, initial gamma, residual gamma, and internal (inhaled and ingested) alpha, beta, and gamma shall

be considered. However, doses will be reported as gamma dose, neutron dose, and internal dose. To the extent to which the information is available, the responses will address the following questions:

(a) Can it be documented that the veteran was a test participant? If so, what tests did he attend and what were the specifics of these tests (date, time, yield (unless classified) type, location and other relevant details)?

(b) What unit was the man in? What were the mission and activities of the units at the test?

(c) To the extent to which the available records indicate, what were his duties at the test?

(d) Can you corroborate the specific information relevant to the potential exposure provided by the claimant to the Veterans Administration and forwarded to the Department of Defense? What is the impact of these specific activities on the claimant's reconstructed dose?

(e) Is there any recorded radiation exposure for the individual? Does this recorded exposure cover the full period of test participation? What are the uncertainties associated with the recorded film badge dose?

(f) If recorded dosimetry data is unavailable or incomplete, what is the dose reconstruction for the most probable dose, with error limits, if available?

(g) Is there evidence of a neutron or internal exposure? What is the reconstruction?

Upon request, the participant or his or her authorized representative will be informed of the specific methodologies and assumptions employed in estimating his or her dose.

## PART 219—PROTECTION OF HUMAN SUBJECTS

Sec.

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28021, June 18, 1991, unless otherwise noted.

### § 219.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 219.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 219.102(e) must be reviewed and approved, in