



# REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

## REGULATORY GUIDE 8.26

*(Draft was issued as OH 714-4, dated August 1979)*

### APPLICATIONS OF BIOASSAY FOR FISSION AND ACTIVATION PRODUCTS

#### A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," states that the Nuclear Regulatory Commission may incorporate in any license certain provisions requiring bioassay measurements as necessary or desirable to aid in determining the extent of an individual's exposure to concentrations of radioactive material. As used by the Commission, the term bioassay includes *in vivo* measurements as well as measurements of radioactive material in excreta.

This guide identifies the bases that will be used by the NRC staff in evaluating the need for license provisions to require bioassay programs in installations where employees may be subject to internal radiation exposure from the inhalation or ingestion of fission or neutron activation products. The guide also describes methods acceptable to the NRC staff for determining the persons to be included in a bioassay program, the sampling and measurement techniques to be used, the frequency of bioassay measurements to be made, actions to be taken based on designated levels of internal radioactivity, estimations of internal dose to be calculated from bioassay measurements, and record systems to be maintained appropriate to such bioassay programs.

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The NRC issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public.

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## B. DISCUSSION

Working Group N343, a subcommittee of the Health Physics Society Standards Committee, developed a standard<sup>1</sup> for the American National Standards Institute (ANSI) presenting requirements and recommended practices for the surveillance and protection of employees of licensee installations where fission or activation products may be processed or handled in unencapsulated form. This standard was approved by ANSI in January 1979, and NRC staff review has indicated that the standard's provisions in these areas are adequate as modified or supplemented by the regulatory position of this guide.

## C. REGULATORY POSITION

Bioassay programs that meet the requirements and recommendations of ANSI Standard N343-1978 are acceptable for complying with license provisions pursuant to § 20.108 of 10 CFR Part 20 that may require bioassay for any fission or activation product radionuclides listed in this standard. However, for compliance with NRC requirements, paragraph 6.2.2 of the standard dealing with the selection of individuals to be included in the bioassay program should be interpreted as follows:

“All facility personnel who routinely enter bioassay areas for routine operations or for maintenance work are to be scheduled for *in vivo* measurements in accordance with the minimum bioassay program. For nonroutine entries the health physicist or radiation protection manager<sup>2</sup> shall determine the need on a case basis.”

The ANSI standard recommends in Sections 11, “Calculational Methods” and 12, “Interpretation of Results for Diagnostic Purposes,” that “As more representative morphological and metabolic parameters become available, these should be substituted for the ones suggested here” and that “The organ burdens, retention functions, dose rates, and dose commitments shall be based on ICRP models when specific data are unavailable.” Since the International Commission on Radiological Protection (ICRP)<sup>3</sup> methods presented in the ANSI standard were developed, more recent data and methods of calculation (Refs. 1-17) have been published by the scientists involved in the continued development of methods of internal dosimetry, including some new calculations for the ICRP and the Medical Internal Radiation Dose (MIRD) Committee of the Society of Nuclear Medicine.<sup>3</sup>

In cases where any direct or indirect bioassay measurements indicate that an individual may receive more than 10 percent of any permissible annual intake derived from concentrations specified in NRC regulations, the additional references listed in this guide, as well as the methods and references of the ANSI standard, should be consulted to determine the most accurate methods of internal dose assessment for the radionuclides and conditions of exposure involved. In some cases, more than one method of evaluation may be required to properly assess internal exposures. All methods of internal dose assessment, as well as all data used in the assessments, should be clearly referenced and recorded as part of the records systems recommended in Section 16, “Records,” of the ANSI standard. Calculations for

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<sup>1</sup> Copies of ANSI N343-1978, “Internal Dosimetry for Mixed Fission and Activation Products,” are available from the American National Standards Institute, 1430 Broadway, New York, N.Y. 10018.

<sup>2</sup> The title “Radiation Protection Manager” is used synonymously with radiation safety officer by many licensees; other titles are equally acceptable.

<sup>3</sup> Publications of the International Commission on Radiological Protection (ICRP) listed in this guide, in the ANSI standard, or to be published in the future may be ordered from Pergamon Press, Inc., Maxwell House, Elmsford, N.Y. 10523 or through bookstores in the United States. Publications of the MIRD Committee may be obtained from Medical Internal Radiation Dose (MIRD) Committee, Society of Nuclear Medicine, 475 Park Avenue South, New York, N.Y. 10016.

each individual may be recorded together with references to the standard model, where a number of individuals may have been subject to similar exposure conditions.

## **D. IMPLEMENTATION**

The purpose of this section is to provide information to applicants regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the NRC staff will use the methods described herein after December 1, 1980, in the evaluation of bioassay programs included in license applications.

If an applicant or licensee wishes to use the methods described in this regulatory guide on or before December 1, 1980, the pertinent portions of the application or the licensee's performance will be evaluated on the basis of this guide.

## REFERENCES<sup>4</sup>

1. L. T. Dillman, and F. C. von der Lage, *Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation Dose Estimation*, NM/MIRD Pamphlet No. 10, Society of Nuclear Medicine, New York, September 1975.
2. M. J. Martin, *Nuclear Decay Data for Selected Radionuclides*, ORNL-5114, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, March 1976.
3. D. C. Kocher, *Nuclear Decay Data for Radionuclides Occurring in Routine Releases from Nuclear Fuel Cycle Facilities*, ORNL/NUREG/TM-102, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, August 1977.
4. M. R. Ford, S. R. Bernard, L. T. Dillman, and S. B. Watson, *Internal Dosimetry and Methods of ICRP-Part 1*, ORNL/NUREG/TM-315, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, June 1979.
5. W. S. Snyder, M. R. Ford, G. G. Warner, and S. B. Watson, *A Tabulation of Dose Equivalent per Microcurie-Day for Source and Target Organs of an Adult for Various Radionuclides: Part I*, ORNL-5000, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, 1974.
6. W. S. Snyder, M. R. Ford, G. G. Warner, and S. B. Watson, *A Tabulation of Dose Equivalent per Microcurie-Day for Source and Target Organs of an Adult for Various Radionuclides: Part II*, ORNL-5000, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, 1975.
7. S. B. Watson, W. S. Snyder, and M. R. Ford, *TIMED: A Computer Program for Calculating Activity of a Radionuclide in the Organs of the Human Body at a Given Time, t, After Deposition*, ORNL/CSD/TM-17, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, 1976.
8. W. S. Snyder, M. R. Ford, G. G. Warner, and S. B. Watson, "S", *Absorbed Dose per Cumulated Activity for Selected Radionuclides and Organs*, NM/MIRD Pamphlet No. 11, Society of Nuclear Medicine, New York, 1975.
9. N. Adams, B. W. Hunt, and J. A. Reissland, *Annual Limits of Intake of Radionuclides for Workers, NRPBR82*, National Radiological Protection Board, Harwell, Didcot, Oxon, OX 11 0RQ, England, October 1978.
10. G. G. Killough, D. E. Dunning, Jr., S. R. Bernard, and J. C. Pleasant, *Estimates of Internal Dose Equivalent to 22 Target Organs for Radionuclides Occurring in Routine Releases from Nuclear Fuel-Cycle Facilities*, Vol. 1, ORNL/NUREG/TM-190, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, June 1978.
11. G. G. Killough, D. E. Dunning, Jr., and J. C. Pleasant, *INREM II: A Computer Implementation of Recent Models for Estimating the Dose Equivalent to Organs of Man from an Inhaled or Ingested Radionuclide*, ORNL/NUREG/TM-84, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, 1978.

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<sup>4</sup> The ICRP-10 series of reports describing methods of calculating internal dose from bioassay data is being revised and updated. Information on published ICRP reports may be obtained from Pergamon Press, Inc., Maxwell House, Elmsford, N.Y. 10523 or through bookstores in the United States.

12. D. E. Dunning, Jr., J. C. Pleasant, and G. G. Killough, *S FACTOR: A Computer Code for Calculating Dose Equivalent to a Target Organ per Microcurie-Day Residence of a Radionuclide in a Source Organ*, ORNL/NUREG/TM-85, Oak Ridge National Laboratory, Oak Ridge, Tennessee, 37830, 1977.
13. W. S. Snyder, M. R. Ford, and S. B. Watson, *A Computer Program for Estimating Microcurie-Days of a Radionuclide in the Organs of the Human Body*, Health Phys. Div. Annu. Prog. Rep., ORNL-5046, p. 225, June 30, 1975.
14. K. W. Skrable, C. S. French, G. E. Chabot, and A. Major, "A General Equation for the Kinetics of Linear First Order Phenomena and Suggested Applications," *Health Phys.*, vol. 27, pp. 155-157, 1974.
15. K. W. Skrable, G. E. Chabot, J. Y. Harris, and C. S. French, "Dosimetric Model for the Gastrointestinal Tract," *Health Phys.*, vol. 28, pp. 411-427, 1975.
16. K. W. Skrable, "Internal Dosimetry and Action Levels Applicable to *In Vivo* Counting and Other Bioassay Procedures," unpublished, October 1979 (available from Dr. Kenneth W. Skrable, University of Lowell, One University Avenue, Lowell, Massachusetts 01854).
17. L. T. Dillman, "EDISTR-A Computer Program to Obtain a Nuclear Decay Data Base for Radiation Dosimetry," ORNL/TM-6689, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37830, January 1980 (available from the National Technical Information Service, Springfield, VA 22161).

## **VALUE/IMPACT STATEMENT<sup>5</sup>**

ANSI Standard N343-1978, "Internal Dosimetry for Mixed Fission and Activation Products," was developed by the Health Physics Society's Standards Committee (HPSSC) on a high-priority basis and was approved by the American National Standards Institute (ANSI) for publication in 1979.

This guidance is needed to facilitate the licensing process, since different methods of measurement and interpretation for these nuclides are carried out in different licensee facilities. NRC staff members have participated in the work performed by the HPSSC working group and have collected NRC staff comments on the draft standards for ANSI. This endorsement of ANSI N343-1978 by a regulatory guide was determined to be the only viable option for alleviating present uncertainties and conflicts in judgment between various licensees and various professionals in establishing bioassay requirements and interpreting compliance for exposures to different fission and activation product radionuclides. This guide replaces interim informal guidance provided by the NRC staff prior to the guide's issuance.

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<sup>5</sup> No change in the Draft Value/Impact Statement (published in August 1979 with Draft Guide OH 714-4) was suggested by the public comments or other information received by the NRC staff. These drafts are available for inspection at the NRC Public Document Room, 1717 H Street NW., Washington, D.C.