New York State Department of Health
Bureau of Environmental Radiation Protection

# RADIATION GUIDE 10.3

# GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LABORATORY PROGRAMS OF LIMITED SCOPE

## INTRODUCTION

A. 1. Purpose of Guide

This guide describes the type of information that should be submitted in applications for specific licenses of limited scope for the possession and use of radioactive material by laboratories. It does not apply to applications for specific licenses of broad scope, licenses for source or special nuclear materials, or licenses for kilocurie irradiation sources. It includes the general principles that will be considered in evaluating an applicant's proposed radiation safety measures. This type of license is provided for under Section 16.100, New York State Sanitary Code (10 NYCRR 16).

The New York State Department of Health will normally issue a single license to cover the laboratory's entire radioisotope program. Separate licenses are not normally issued to different departments of a laboratory, nor are they issued to individuals associated with the laboratory.

The applicant should carefully study the regulations and this guide, and should submit all information requested. The Department will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

Three general principles that will be considered in evaluating proposed radiation safety measures are recognition by the laboratory of:

1) The management's* responsibility for the safety of employees and the public;

2) Its responsibility for maintaining off-site releases as low as is reasonably achievable (ALARA) and avoiding significant increases in environmental radioactivity: and

3) Its responsibility for minimizing exposures to employees.

* Management is defined as those persons authorized by the charter of the institution to make its policies and direct its activities.

2. Purpose of Appendices to Guide

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through L to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and adopt them as written whenever possible. If you are unable to adopt a particular procedure as written submit a copy of the procedure in the guide with your changes indicated in red ink. You must keep copies of these procedures with the license document when it is issued since they will be made a part of the license at that time.

B. Applicable Regulations

All regulations pertaining to this type of license are found in Title 10, Chapter 1, Part 16, of the New York Code of Rules and Regulations (10 NYCRR 16). Chapter 1 is entitled the "State Sanitary Code" and Part 16 is entitled, "Ionizing Radiation." The statutory authority for the rules and regulations is found in the New York State Public Health Law, Section 225.

C. As Low As is Reasonably Achievable (ALARA)

Item (a) of 10 NYCRR 16.5 requires that persons who operate or permit the operation of radiation installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 16 as is reasonably achievable. License applicants should give consideration to the ALARA philosophy in the development of plans for work with radioactive materials.

D. Types of Radioactive Materials Licenses

Specific Licenses - Limited Scope

Specific licenses of limited scope are issued to institutions which use radioactive materials in moderate or small quantities. Such licenses specify the radioisotopes, the use of the material, and the person who is the primary user of the materials.

Specific Licenses - Broad Scope

If the institution has an extensive radioisotope program with a need for a great variety of radionuclides for many uses, it may wish to apply for a specific license of broad scope. Such a license authorizes multiple quantities of many types of radioactive materials for unspecified uses. Such programs operate under the supervision of a radiation safety committee. Individual users are not named on the license. All uses and users are approved by the institution's radiation safety committee. This type of license is not appropriate for most institutions using radioactive materials. Further information on this type of license can be obtained from the New York State Department of Health.

## FILING AN APPLICATION

A license application for specific licenses for laboratory use should be submitted on Form GEN 307B, "Application for Radioactive Materials License" and appropriate attachments. The applicant should complete all items on the application form in sufficient detail for the review staff to determine that the applicant's equipment, facilities, personnel training and qualifications, and radiation safety program are adequate to protect health and minimize danger to life and property.

For items 5 through 25, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to to 8-1/2 x 11 inches.

One copy of the application, with all attachments, should be retained by the applicant, since the license will require as a condition that the licensee follow the statements and representations set forth in the application and any supplement to it. The original and one copy should be mailed to the Bureau of Environmental Radiation Protection, New York State Department of Health, 2 University Place, Room 325, Albany, New York 12203.

## CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form GEN 307B.

Item 1a Enter the name and corporate address of the laboratory and the telephone number of administration.

Item 1b List all addresses and locations where radioactive material will be used or stored if other than that in Item 1a, e.g., laboratory-owned farm or research station. A post office box number should not be stated as the address for a place of use. These addresses and locations will become part of the license conditions, if the license application is approved, and the addresses or locations at which radioactive materials or radioactive wastes are located or stored may not be changed without obtaining a license amendment.

Item 2 Enter the name and telephone number (including area code) of the individual who knows your proposed radioactive materials program and can answer questions about the application. This should be a staff member and not a consultant.

Item 3 Indicate whether the application is for a new license, an amendment to an existing license, or a renewal of an existing license.

Item 4 State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. If the radiation safety officer is assisted by a consultant or part-time employee, state the consultant's name and describe his/her duties, responsibilities, and the amount of time to be devoted to the radiation safety program.

Item 5 List all individuals who will use or directly supervise the use of radioactive material. Give the title or position of each person.

Item 6a List each radionuclide to be used, and specify the particular nuclides to be licensed for use by each individual named in item 5.

Item 6b List the chemical and physical form and maximum quantity (in millicuries) of each radionuclide to be possessed at any one time. State separate possession limits for each chemical and physical form requested, e.g., iodine-131 as iodide and labeled proteins. List the manufacturer, model number, and quantity for all sealed sources. The possession limit for each radionuclide should include material held as radioactive wastes.

Item 7 Describe the intended use for each radionuclide and form listed in items 6a and 6b. Any use of radioactive material in animals should be indicated. (Human use applications should be filed separately.)

Item 8a Radiation Safety Officer - Section 16.5, New York State Sanitary Code (10 NYCRR 16) requires that a Radiation Safety Officer be appointed. The Radiation Safety Officer is responsible for the day-to-day operation of the radiation safety program within the institution. A description of his/her training and experience in radiation protection and the use of radioactive material should be provided, along with a curriculum vitae.

The Radiation Safety Officer should have, as minimum qualifications, a bachelors degree in science, formal training in radiological health (e.g., college level or its equivalent) and should have specific experience in radiation protection with the types, quantities and uses of the radioactive material requested in the application. Submit an outline of the candidate's training and experience in radiological health and the use of radioactive materials. Include on-the-job and formal trainng, where it was obtained, dates and durations and the topics covered. Also include experience with the use of materials; the radionuclides used, the quantities handled and the type of process. Experience in the specific functions the Radiation Safety Officer will perform (e.g. wipe-testing, leak-testing, thyroid bioassay, waste handling, meter calibration) should be individually listed.

A statement must be included delineating the Radiation Safety Officer's duties, responsibilities and authority for carrying out the radiation safety program. The extent of the Radiation Safety Officer's responsibility and authority will depend on the scope of the proposed program; however, the following should be considered for inclusion in your statement:

(1) General surveillance over all activities involving radioactive material, including routine monitoring and special surveys of all areas in which radioactive material is used.

(2) Determining compliance with rules and regulations, license conditions, and the conditions of project approval specified by the radiation safety committee.

(3) Monitoring and maintaining absolute and other special filter systems associated with the use, storage or disposal of radioactive material.

(4) Furnishing consulting services on all aspects of radiation safety to personnel at all levels of responsibility.

(5) Receiving, delivering and opening all shipments of radioactive material arriving at the institution and receiving, packaging and shipping all radioactive material leaving the institution.

8a Continued

(6) Distributing and processing personnel monitoring equipment, determining the need for bioassays, keeping personnel exposure and bioassay records, and notifying individuals and their supervisors of exposures approaching maximum permissible amounts and recommending appropriate remedial action.

(7) Conducting training programs and otherwise instructing personnel in the proper procedures for the use of radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.

(8) Supervising and coordinating the radioactive waste disposal program, including keeping waste storage and disposal records, and monitoring effluents.

(9) Storing all radioactive materials not in current use, including wastes.

(10) Performing leak tests on all sealed sources.

(11) Maintaining an inventory of all radioisotopes at the institution and limiting the quantity of radionuclides at the institution to the amounts authorized by the license. The inventory should include the name of the person responsible for each quantity of radioisotope, where it will be used or stored, and the date the quantity was delivered to that person. Items are removed from the inventory by showing how and when the radioisotope was disposed of.

(12) The authority to terminate immediately a project that is found to be a threat to health or property.

(13) Maintaining other records not specifically designated above (e.g., receipt, transfer and survey records as required by Section 16.14 of 10 NYCRR 16).

Item 8b Radiation Safety Committee - The New York State Department of Health requires that the applicant for an institutional license, which names more than one person as individual users, appoint a radiation safety committee. The committee should include persons expert in radiobiology, radiochemistry or radiation physics, a person experienced in assay of radionuclides and protection against ionizing radiation, usually the radiation safety officer, a person representing management, a representative from each department using radioactive materials, and other persons whose fields of expertise complement the functions of the committee. One of the main functions of the radiation safety committee is to administer the institution's radioactive materials program. The committee should have the authority and responsibility for approval and disapproval of all proposals for radionuclide use prior to purchase of the materials.

Item 8b Continued

The following information concerning the committee must be submitted:

(1) A list of members of the committee. The committee members who have an essential radiation safety function, such as the chairman and the radiation safety officer, should be listed by name. Members with a less important safety function, e.g., administration representative, may be listed by title and minimum qualifications.

(2) A description of each member's training and experience with radiation and radioactive material.

Appendix A to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 9a Training and Experience - Submit the curriculum vitae and a description of experience with radioactive materials for each individual listed in item 5. Include the radionuclides used, the quantities handled and the type of process.

Item 9b Personnel Training Program - Appendix B to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item10a Instruments - Submit a list of all radiation detection instrumentation available. Appendix C to this guide contains a form that may be used to describe the instruments. Complete this form and return with application.

Item 10b (1) Calibration of Instruments - If survey meter calibrations are performed at your facility. You must submit your procedures. Appendix D to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

If your survey meters are sent out for calibration, submit a statement that calibrations will be performed by persons licensed to perform this service by the U.S. Nuclear Regulatory Commission or an Agreement State and that a copy of this license will be kept on file with the calibration certificates.

(2) Quantitative Measuring Instruments - Instruments that will be used for quantitative measurements to determine compliance with Department regulations (e.g., leak-test measurements, effluent monitoring) should be calibrated at six-month intervals. A description of the procedure for calibration of such instruments should be submitted and should include:

10b(2)

(a) the manufacturer and model number of the source(s);
(b) the nuclide and quantity of radioactive material in the source(s);
(c) the accuracy of the source(s);

(d) the step-by-step procedures for calibration, including associated radiation procedures; and

(e) the name(s) and pertinent experience of person(s) who will perform the calibrations.

Item 11 Facilities and Equipment - Describe the facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation and measurement of radioactive materials. A diagram should be submitted showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagram should also include schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Diagrams should be drawn to a specified scale, or dimensions should be indicated. The locations of the facilities and equipment should be specified with respect to the addresses and locations given in item 1b.

Item 12 Procedures for Ordering and Receiving Radioactive Material - Appendix E to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 13 Procedures for Package Opening - Appendix F to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 14 General Rules for the Safe Use of Radioactive Material - Describe your rules for the safe use of radioactive material. Appendix G to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 15 Spill Procedures - Appendix H to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 16 Area Survey Procedures - Appendix I to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 17 Waste Disposal - Appendix J to this Guide contains general guidance and model procedures for waste disposal. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 18 Not Applicable

Item 19 Not Applicable

Item 20 Not Applicable

Item 21 Procedures and Precautions for Use of Radioactive Materials in Animals - Submit the procedures to be followed if radioisotopes will be used in animals, including: (a) a description of the animal housing facilities; (b) a copy of instructions provided to animal caretakers for the handling of animals, animal waste, and animal carcasses; (c) instructions for cleaning and decontaminating animal cages; and (d) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material. Instructions to animal caretakers should reflect the types of studies done at the institution.

Item 22 Other Procedures and Precautions for Use of Radioactive Materials Specified in item 6b - Clearly state any additional radiation safety procedures to be followed while individuals are using the materials listed in item 6b, e.g., air sampling,* other special surveys, bioassays, leak-testing sealed sources, including radiation safety procedures.

Bioassays may be required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Guidance on bioassay programs for iodine-131 and iodine-125 including the levels and types of handling for which bioassays are indicated, are provided in U.S. Nuclear Regulatory Commission Guide 8.20, "Applications of Bioassays for I-125 and I-131" and Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program." Copies of these guides are attached. If you propose to use bioassays less conservatively than is recommended in the guides discussed above, you should state your rationale. Submit your bioassay policy.

Leak-Testing of Sealed Sources - Is required by Section 16.10 (a) (4), New York State Sanitary Code, (10 NYCRR 16). Appendix K to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink. If an outside service analyzes leak-test samples submit a statement that the service will be performed by persons licensed to do so by the U.S. Nuclear Regulatory Commission or an Agreement State and that a copy of this license will be kept on file with the leak-test reports.

*NOTE: Releases to the environment are regulated by the New York State Department of Environmental Conservation in 6 NYCRR Part 380. For further information contact: New York State Department of Environmental Conservation, Division of Hazardous Substance Regulation, Bureau of Radiation, 50 Wolf Road, Albany, New York 12233-0001

Item 23 Personnel Monitoring Program - Appendix L to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

Item 24 Not Applicable

Item 25 Not Applicable

Item 26 Certificate - The application should be signed by the President, or Chief Executive Officer. Identify the title of the office held by the individual who signs the application.

## AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including type of monitoring and survey instruments), procedures, authorized users or radiation safety officer, or radioactive material to be used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific, and should identify the pertinent information by date, page and paragraph.

## RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until action on the application has been taken by the New York State Department of Health, as provided for in Section 16.105, New York State Sanitary Code (10 NYCRR 16).

Renewal applications should be filed on Form GEN 307B, appropriately supplemented, should contain complete and up-to-date information about the applicant's current program, should meet all licensing and regulatory requirements in effect at the time of renewal, and should be signed and dated by a representative of the licensee's administrative management. Renewal applications should also include the users' training and experience or make a clear and specific reference to previous applications on which individual users received approval.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users).

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original and one copy to the New York State Department of Health, Bureau of Environmental Radiation Protection, 2 University Place, Room 325, Albany, New York 12203.

## LICENSE TERMINATION REQUESTS

Submit a signed Form GEN 322 indicating the disposition of the radioactive material. Form GEN 322 is available from the New York State Department of Health, Bureau of Environmental Radiation Protection, Empire State Plaza, 2 University Place, Room 325, Albany, New York 12203.

Submit a survey showing that all previously occupied areas are free of contamination and all sources of radioactive material have been removed in accordance with Section 16.10, New York State Sanitary Code (10 NYCRR 16). A decontamination guide is available from the New York State Department of Health, Bureau of Environmental Radiation Protection, 2 University Place, Room 325, Albany, New York 12203.

Such submissions must be made at least 30 days prior to relinquishing possession or control of premises where radioactive material is or has been stored or used.

LIST OF APPENDICES

## APPENDIX A

### RADIATION SAFETY COMMITTEE

### MODEL PROCEDURE FOR ESTABLISHING RADIATION SAFETY COMMITTEE

Responsibility

The Committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with Department regulations and the conditions of this license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with Department regulations and the conditions of the license.

Duties

The Committee shall:

1. Be familiar with all pertinent New York State Health Department regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of all individuals who use radioactive material and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with New York State Health Department regulations and the conditions of the license.

3. Be responsible for monitoring the institution's program to maintain individual and collective doses as low as reasonably achievable.

4. Review semi-annually, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive materials.

5. Establish a table of investigational levels for occupational radiation exposure, which when exceeded, will initiate an investigation and consideration of action by the Radiation Safety Officer.

6. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., security and housekeeping personnel) are properly instructed as required by Section 16.13, New York State Sanitary Code (10 NYCRR 16).

7. Review and approve all requests for use of radioactive material within the institution.

8. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

9. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with New York State Health Department regulations and the conditions of the license. The review shall include an examination of all records, reports from the Radiation Safety Officer, results of New York State Health Department inspection, written safety procedures, and the adequacy of the institution's management control system.

10. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

11. Maintain written records of all Committee meetings, actions, recommendations, and decisions.

12. Ensure that the radioactive materials license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, radioactive material, possession limits, and personnel, as specified in the license.

Meetings

1. The Radiation Safety Committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.

2. A quorum shall consist of at least one-half of the Committee's membership, including the Radiation Safety Officer and the management representative.

## APPENDIX B

## MODEL PERSONNEL TRAINING PROGRAM

It may not be assumed that safety instruction has been adequately covered by prior training at other institutions, even experienced professionals will need instruction in your institution's procedures and the conditions of your license. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction should be written and implemented.

### Model Program

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used or stored.

3. Potential hazards associated with radioactive material in each area where the employees will work.

4. Appropriate radiation safety procedures.

5. Licensee's in-house work rules.

6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.

7. Appropriate response to emergencies or unsafe conditions.

8. Worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by Section 16.13, New York State Sanitary Code (10 NYCRR 16).

Records that Document Training

Records of initial and refresher training will be maintained for five years and will include:

1. the name of the individual who conducted the training;

2. the names of the individuals who received the training;

3. the dates and duration of the training session; and

4. a list of the topics covered.

## APPENDIX C

### INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name _____

      Manufacturer's model number _____

      Number of instruments available _____

      Minimum range _____ mR/hr to _____ mR/hr

      Maximum range _____ mR/hr to _____ mR/hr

   b. Manufacturer's name _____

      Manufacturer's model number _____

      Number of instruments available _____

      Minimum range _____ mR/hr to _____ mR/hr

      Maximum range _____ mR/hr to _____ mR/hr

2. Other instruments used for quantitative measurement procedures (e.g., liquid scintillation counter, well counter, velometer)

| Type of Instrument | Manufacturer's Name | Model No. |
|---|---|---|

## APPENDIX D

### MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

#### Model Procedure

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of cesium-137, 21 millicuries of cobalt-60, and 34 millicuries of radium-226.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. The following three kinds of scales are frequently used on survey meters:

   a. Meter on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

8. b. Meters that have a multi-decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of scale.

   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

    a. The owner or user of the equipment.

    b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector.

    c. A description of the calibration source, including exposure rate at a specified distance on a specified date.

    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument.

    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument).

    f. The angle between the radiation flux field and detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector. For instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument.

    g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure.

    h. The apparent exposure rate from the check source.

    i. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information will be attached to the instrument as a calibration sticker or tag:

    a. The source that was used to calibrate the instrument.

    b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument).

    c. For each scale or decade, one of the following as appropriate:

        1) the average correction factor;

        2) a graph or graphs from which the correction factor for each scale or decade may be deduced; or

        3) an indication that the scale was checked for function but not calibrated, or an indication that the scale was inoperative.

    d. The angle between the radiation flux and the detector during the calibration.

    e. The apparent exposure rate from the check source.

NOTE: One-word reminders or symbols that are explained on the Survey Meter Calibration report may be used on the calibration sticker.

On the following page is a form you may want to use.

## Survey Meter Calibration Report

Owner:_____ Department:_____

Manufacturer:_____ Type: o Ion Chamber o GM o NaI(Tl) o _____

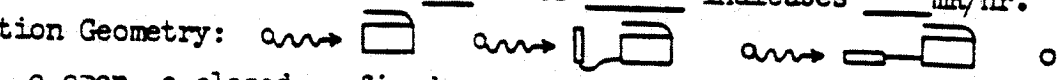
Meter model:_____ Meter S/N:_____ Probe model:_____ Probe S/N:_____

Calibration Source: ___mCi of _____. ____mR/hr at __in on _____, 19__.

Instrument checks: Battery check:___mR/hr or _____

Constancy check: o integral check source indicates ____mR/hr.

o ___mCi of _____ indicates ____mR/hr.

Calibration Geometry:  o

Window: o open o closed o fixed

| dist (feet) | mR/hr today | Scale: Rdng | CorFac | Scale: Rdng | CorFac | Scale: Rdng | CorFac | Scale: Rdng | CorFac |
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Correction Factors: _____ _____ _____ _____

Name:_____

Date:_____

Calibration Sticker

Cald ___-___-___ with _____
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scale CorFac
_____ _____ bat:"__mR/hr"
_____ _____
_____ _____ chk:"__mR/hr"

## APPENDIX E

## MODEL PROCEDURE FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

### Model Procedure

1. The Radiation Safety Officer will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

   The standard purchase order, or purchase request, used at this institution will have a box that must be checked indicating that the requested item is, or is not, radioactive material. The purchasing agent will not process any order where radioactive material is indicated unless it is countersigned by the Radiation Safety Officer.

2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:

   a. Written records will be used that identify the isotope, compound, activity levels, and supplier.

   b. The written records will be referenced when opening or storing radioactive shipments.

   c. It is essential that written records be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive materials directly to .*

4. During off-duty hours security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum.

*The appropriate information for your facility should be supplied in this space.

Sample Memorandum*

MEMORANDUM TO: Security Personnel

FROM: John Jones, Administrator

SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive between 4:30 PM and 7:00 AM, or on Sundays, shall be signed for by the Security Guard on duty and taken immediately to the Radiation Safety Office. Unlock the door, place the package on top of the counter immediately to the right of the door, and re-lock the door.

If the package is wet or appears to be damaged, immediately contact the Radiation Safety Officer. Ask the carrier to remain at the institution until it can be determined that neither he, nor the delivery vehicle, are contaminated.

RADIATION SAFETY OFFICER _____

OFFICE TELEPHONE _____ HOME TELEPHONE _____

*Submit a copy of your own institution's memorandum.

## APPENDIX F

## MODEL PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

### Model Procedure

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the A quantities specified in 49 CFR 173.435. They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of Section 16.16 (a) and (e), New York State Sanitary Code (10 NYCRR 16). The Department will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 square centimeters (22,000 dpm) or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for any sign of damage (i.e., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If it is higher than usual, stop and notify the Radiation Safety Officer.

   d. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip and label on container.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, or discoloration of packaging material).

2. e. If there is any reason to suspect contamination, wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (i.e., dpm/100 square centimeters, etc.). Check wipes with a thin-end window GM survey meter, and take precautions against the spread of contamination as necessary.

   f. Monitor the packing material and packages for contamination before discarding.

      (1) If contaminated, treat as radioactive waste.

      (2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page), or a form containing the same information.

Radioactive Shipment Receipt Record

1. P.O. No. _____ Survey Date _____ Time _____

   Surveyor _____

2. Condition of the Package:

   ____ OK

   ____ Other (explain)

3. Radiation Units of Label: _____ units (mR/hr)

4. Measured Radiation Levels:

   a. Package Surface _____ mR/hr

   b. 3 feet or 1 meter from Surface _____ mR/hr

5. Do Packing Slip and Vial Contents Agree?

   a. Radionuclide ____ Yes ____ No Difference _____

   b. Amount ____ Yes ____ No Difference _____

   c. Chemical Form ____ Yes ____ No Difference _____

6. Wipe Results From:

   a. Outer _____ CPM - _____ (efficiency) = _____ DPM

   b. Final Source Container _____ CPM - _____ (efficiency) = _____ DPM

7. Survey Results of Packing Material and Cartons _____ mR/hr, CPM

8. Disposition of Package After Inspection _____

9. If Department/Carrier Notification Required, Give Time, Date, and Persons Notified

_____ _____

Signature Date

## APPENDIX G

## MODEL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

These rules must be posted as required by Section 16.13 (b), New York State Sanitary Code (10 NYCRR 16).

### Model Rules

1. Prior to performing operations with quantities of radioactive material which may produce significant external or internal exposure, attention shall be given by the user to precautionary measures including the use of remote handling devices, hoods, shielding, etc. The Radiation Safety Officer must be consulted before beginning any new use of radioactive material.

2. There shall be no eating, drinking, applying cosmetics or preparation of food in any location where unsealed sources of radioactive materials are used or stored.

3. Smoking is prohibited in locations where unsealed sources of radioactive materials are used or stored.

4. Do not store food, drink, or personal effects with radioactive material.

5. Pipetting of radioactive solutions by mouth is prohibited.

6. Segregate pipetting devices used with radioactive materials from those used with non-radioactive solutions.

7. Lab coats and disposable gloves shall be worn during operations involving the handling of unsealed sources of radioactive material. The lab coat and gloves should be removed before leaving the laboratory. Care must be taken such that other items (e.g., pens, pencils, notebooks, door knobs, telephones, etc.) are <u>not</u> handled with gloves used during work with radioactive materials.

8. Work which may result in contamination of work surfaces shall be done over plastic-backed absorbent paper. Trays made of impervious materials (i.e., stainless steel, porcelain-coated, etc.) and lined with absorbent paper provide excellent work arrangements to help prevent the spread of contamination.

9. Work surfaces and personnel should be monitored after working with radioactive materials.

10. Where there has been a spill of radioactive material (see posted Spill Procedures) which may have produced contamination of the person or clothing, both the person and the clothing shall be monitored. Personnel contamination shall be removed as soon as possible.

    Where contamination above action levels is noted during a laboratory survey decontamination must be immediately initiated by the user.

11. After working with unsealed sources of radioactive material, hands should be monitored and washed before leaving the laboratory.

12. Objects and equipment that may have been contaminated with radioactive material shall be surveyed and demonstrated to be free of contamination prior to their removal from a laboratory, or transferred to other laboratories, repair shops, surplus, etc. If found to be contaminated, such items must be decontaminated as soon as practical.

13. If personnel monitoring devices (whole-body or ring badge) have been issued to you for your work with radioactive material, they must be worn at all times when in areas where these materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. Personnel monitoring devices should be stored in a designated low background area when they are not being worn to monitor occupational exposures. They should <u>not</u> be left on your lab coat or shared by another individual.

14. Dispose of radioactive waste only in the manner designated by the Radiation Safety Officer and maintain records as instructed.

15. Store radioactive materials in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

16. Always transport radioactive material in shielded containers.

## APPENDIX H

## MODEL SPILL PROCEDURES

These procedures must be posted as required by Section 16.13 (b), New York State Sanitary Code (10 NYCRR 16.

Minor* Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as contaminated gloves.

4. SURVEY: With a low-range thin-window GM survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major* Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

*Define Minor and Major as they apply to your facility

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

7. The Radiation Safety Officer will supervise the clean-up of the spill and will complete a report.

RADIATION SAFETY OFFICER: _____**

OFFICE PHONE: _____ HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY THE RADIATION SAFETY OFFICER:

_____

_____

_____

_____

**The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

# APPENDIX I

## MODEL PROCEDURE FOR AREA SURVEYS

### Model Procedure

1. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.

2. Waste storage areas and all other laboratory areas will be surveyed weekly.

3. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sensitive enough to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sensitive enough to detect 1000\dpm per 100 square centimeters for the contaminant involved. Wipes made of "high background" areas will be removed to a low background area for measurement.

4. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to a location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

5. Area will be cleaned if the contamination level exceeds 2000 dpm/100 square centimeters.

# APPENDIX J

## WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, New York State Department of Health is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with Section 16.8, New York State Sanitary Code (10 NYCRR 16).

### General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability).

5. In New York State the Department of Environmental Conservation regulates releases to the environment and has enacted regulations on the transport of low-level radioactive waste in New York State (6 NYCRR Part 381). These regulations require that a properly executied manifest and a valid transport permit issued by Department of Environmental Conservation accompany all waste shipments. For further information contact:

   New York State Department of Environmental Conservation
   Division of Hazardous Substance Regulation
   Bureau of Radiation
   50 Wolf Road
   Albany, New York 12233-0001

### MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 16.8(c), New York State Sanitary Code (10 NYCRR 16). Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Releases to the environment are regulated by the New York State Department of Environmental Conservation in 6NYCRR Part 380. You should be conversant with those regulations and possible permit requirements. For further information contact New York State Department of Environmental Conservation at the address given above.

3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity. Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet, or manifest, that the transfer agent gave you. You must also comply with regulations issued by the New York State Department of Environmental Conservation (6NYCRR Part 381) relating to waste manifests and transport permits.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173-475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

*Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 16).

# APPENDIX K

## MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

### Model Procedure

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing high-activity sources, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

   a. For small sealed sources, it is easiest to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

   b. For larger sealed sources and devices (survey meter calibrator, irradiators), take the wipe near the radiation port and on the activating mechanism.

   c. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

   a. Select a suitable detector that is sufficiently sensitive to detect 0.005 microcuries. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler is usually necessary.

4. b. Assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum in order to estimate the detection efficiency of the analyzer used to assay the wipe samples.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Calculate the estimated activity in microcuries on the wipe sample.

   e. Continue same analysis procedure for all wipe samples.

   f. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of and the Health Department must be notified.

   g. Record the wipe sample results on the list of sources, and sign and date the list.

# APPENDIX L

## MODEL PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

Personnel monitoring devices should be provided for individuals who are exposed to sources of whole-body radiation, or who handle millicurie quantities of energetic beta or gamma-emitting radionuclides.

### Model Program

1. The Radiation Safety Officer will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records (e.g., pocket ionization chambers, when the monitor of record is a film or TLD).

2. All individuals who are occupationally exposed to radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis. This service must be accredited under NVLAP (a voluntary program for determining that a dosimetry service meets ANSI standards).

3. All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis will consult with the Radiation Safety Officer concerning personnel monitoring before using radioactive materials.

5. Other individuals who are exposed to radiation on an occasional basis, such as security personnel who deliver packages, will not normally be issued exposure monitors.

# APPENDIX M

## BIBLIOGRAPHY


Part 16, New York State Sanitary Code (10 NYCRR 16)

U.S. Nuclear Regulatory Commission Regulatory Guides

Regulatory Guide 8.4, "Direct-Reading and Indirect-Reading Pocket Dosimeters"

Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As is Reasonably Achievable"

Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure"

Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131"

Technical Reports

International Atomic Energy Agency (IAEA)[1] Technical Report Series No. 120, "Monitoring of Radioactive Contamination on Surfaces" 1970

IAEA Technical Report Series No. 133, "Handbook on Calibration of Radiation Protection Monitoring Instruments" 1971

International Commission on Radiological Protection (ICRP)[2] Report No. 12, "General Principles of Monitoring for Radiation Protection of Workers" Pergamon Press, 1969

International Commission on Radiation Units and Measurements (ICRU)[3] Report No. 12, Certification of Standardized Radioactive Sources" 9/12/68

National Council on Radiation Protection Measurements (NCRP)[4] Report No. 48, "Radiation Protection for Medical and Applied Health Personnel" issued 8/1/76

NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection" 1978

NRCP Report No. 58, "A Handbook of Radioactivity Measurement Procedures" 1978


1 IAEA (International Atomic Energy Agency) reports may be obtained from UNIPUB, Inc., P.O. Box 433, New York, NY 10016

2 ICRP (International Commission on Radiological Protection) reports may be obtained from Pergamon Press, Maxwell House, Fairview Park, Elmsford, NY 10523

3 ICRU (International Commission on Radiation Units and Measurements) reports may be obtained from ICRU Publications, P.O. Box 30165, Washington, DC 20014

4 NCRP (National Council on Radiation Protection and Measurements) reports may be obtained from NCRP Publications, P.O. Box 4867, Washington, DC 20014

U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
September 1979

# REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

## REGULATORY GUIDE 8.20

## APPLICATIONS OF BIOASSAY FOR I-125 AND I-131

### A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," indicates that the Nuclear Regulatory Commission (NRC) may incorporate into a license provisions requiring a specific program of bioassay measurements as necessary or desirable to aid in determining the extent of an individual's exposure to concentrations of radioactive material. In certain cases, the requirement of bioassay may also be included in the license by reference to procedures specifying in vivo measurements, measurements of radioactive material in excreta, or both.

This guide provides criteria acceptable to the NRC staff for the development and implementation of a bioassay program for any licensee handling or processing I-125 or I-131. It further provides guidance to such licensees regarding the selection of workers who should participate in a program to detect and measure possible internal radiation exposure. The guide is programmatic in nature and does not deal with measurement techniques and procedures.

### B. DISCUSSION

The topics treated in this guide include determinations of (1) whether bioassay should be performed, (2) frequencies of bioassay, (3) who should participate, (4) the actions to take based on bioassay results, and (5) the particular results that should initiate such actions.

For the user's convenience, the following terms are presented with their definitions as used in this guide:

Bioassay–The determination of the kind, quantity or concentration, and location of radioactive material in the human body by direct (in vivo) measurement or by analysis in vitro of materials excreted or removed from the body

Intake–The total quantity of radioactive material entering the body.

In vivo measurements–Measurement of gamma- or x-radiation emitted from radioactive material located within the body for the purpose of detecting or estimating the quantity of radioactive material present.

In vitro measurements–Measurement of radioactivity in samples of material excreted from the human body.

### C. REGULATORY POSITION

#### 1. Conditions Under Which Bioassay Is Necessary

a. Routine[1] bioassay is necessary when an individual handles in open form unsealed[2] quantities of radioactive iodine that exceed those shown in Table 1 of this guide. The quantities shown in Table 1 apply to both the quantity handled at any one time or integrated as the total amount of activity introduced into a process by an employee over any 3-month period. *

b. When quantities handled in unsealed form are greater than 10% of Table 1 values,

*Lines indicate substantive changes from previous issue.

[1] Routine means here that an individual is assigned on a scheduled and repeatable basis to submit specimens for bioassay or to report for in vivo measurements. Either radiochemical bioassay of urine or in vivo counting is acceptable to the NRC staff for estimating internal radioactivity burdens or intakes. In some cases, however, a licensee may wish to corroborate estimates from urinalysis data with in vivo determinations. Since there are adequate references in the literature to help devise bioassay measurements, this guide does not include recommended analytical procedures. Each installation should adopt procedures or obtain services best suited to its own needs.

[2] See discussion in the footnote to Table 1 of this guide.

routine bioassay may still be necessary under certain circumstances. A written justification for not performing such measurements should be prepared and recorded for subsequent review during NRC inspections whenever bioassay is not performed and the quantities handled exceed 10% of the levels in Table 1.

c. Except as stated in regulatory position 1.e, bioassay is not required when process quantities handled by a worker are less than 10% of those in Table 1.

d. In nuclear reactor installations, employees should be bioassayed by an in vivo count within 30 days after the end of exposure in work locations where concentrations exceeded, or might have exceeded, $9 \times 10^{-9}$ μCi/ml averaged over any 40-hour period. Table 1 and regulatory position 4 regarding frequency of bioassays are not applicable to reactor licensees.

e. Special bioassay measurements should be performed to verify the effectiveness of respiratory protection devices and protective clothing. If an individual wearing a respiratory protective device or protective clothing is subjected to a concentration of I-125 or I-131 (in any form) in air such that his or her intake with no protection would have exceeded the limits specified in paragraph 20.103(a)(1) of 10 CFR Part 20,[3] bioassays should be performed to determine the resulting actual I-125 or I-131 intake. These special bioassay procedures should also be conducted for personnel wearing respirators if for any reason the I-125 or I-131 concentration in air and the duration of exposure are unknown or cannot be conservatively estimated by calculation.

### 2. Participation

All workers handling radioactive iodine or sufficiently close to the process so that intake is possible (e.g., within a few meters and in the same room as the worker handling the material) should participate in bioassay programs described in regulatory position 1.

[3]Multiplying the concentrations given in Appendix B to 10 CFR Part 20, Table I, Column 1, $5 \times 10^{-9}$ μCi/ml for I-125 (soluble) and $9 \times 10^{-9}$ μCi/ml for I-131 (soluble), by $6.3 \times 10^{8}$ ml gives the corresponding quarterly intake of the respective iodines by inhalation. These quarterly intakes would be about 3.2 μCi for I-125 and 5.7 μCi for I-131, which would give a thyroid dose commitment of about 7.5 rems to a 20-gram thyroid integrated over all future time using effective half-lives of 41.8 days for I-125 and 7.6 days for I-131 and using a quality factor (QF) of 1.7 to calculate effective disintegration energy in the case of I-125. (This QF of 1.7 is used for conservatism, even though the International Commission on Radiological Protection (1969) and the National Council on Radiation Protection (1971) have published a QF of 1, because some calculations in more recent scientific literature have suggested the use of QF values higher than 1 for electron or beta energies of 0.03 MeV or less.)

### 3. Types of Bioassays That Should Be Performed

a. Baseline (preemployment or preoperational). Prior to beginning work with radioactive iodine in sufficient quantity that bioassay is specified in regulatory position 1.

b. Routine. At the frequency specified in regulatory position 4.

c. Emergency. As soon as possible after any incident that might cause thyroid uptakes to exceed burdens given in regulatory position 5.a(2), so that actions recommended in regulatory position 5.a(2)(b) can be most effective.

d. Postoperational and with Separation Physical. A bioassay should be performed within 2 weeks of the last possible exposure to I-125 or I-131 when operations are being discontinued or when the worker is terminating activities with potential exposure to these radionuclides.

e. Diagnostic. Followup bioassay should be performed within 2 weeks of any measurements exceeding levels given as action points in regulatory position 5 in order to confirm the initial results and, in the case of a single intake, to allow an estimate of the effective half-life of radioiodine in the thyroid.

### 4. Frequency

a. Initial Routine. Except in situations where thyroid burdens may exceed quantities specified in regulatory position 5.a(2), a bioassay sample or measurement should be obtained within 72 hours following entry of an individual into an area where bioassay is performed in accordance with regulatory positions 1 and 2 (but waiting at least 6 hours for distribution of a major part of the iodine to the thyroid[4]) and every 2 weeks or more frequently thereafter as long as the conditions described in regulatory positions 1 and 2 exist. When work with radioactive iodine is on an infrequent basis (less frequently than every 2 weeks), bioassay should be performed within 10 days of the end of the work period during which radioactive iodine was handled (but not sooner than 6 hours unless emergency actions to obtain an early prognosis and thyroid blocking treatment are appropriate[4]).

b. After 3 Months. When a periodic measurement frequency has been selected in accordance with regulatory position 4.a, it may be changed to quarterly if, after 3 months, all the following conditions are met:

(1) The average thyroid burden for each individual working in a given area was

[4]NCRP Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," National Council on Radiation Protection and Measurements, Washington, D.C., August 1, 1977, p. 21.

less than 0.12 μCi of I-125, less than 0.04 μCi of I-131, and less than the corresponding proportionate amount[5] of a mixture of these nuclides during the initial 3-month period:

(2) The quarterly average radioiodine concentration (μCi/ml) in air breathed by any worker (as obtained when measurements of radioiodine concentrations in air are required) does not exceed 25% of the concentration values for "soluble"(s) iodine given in Appendix B to 10 CFR Part 20, Table I, Column 1, ($5 \times 10^{-9}$ μCi/ml for I-125 and $9 \times 10^{-9}$ μCi/ml for I-131), i.e., 25% of these concentrations multiplied by the total air breathed by an employee at work during one calendar quarter, $6.3 \times 10^{8}$ ml, does not exceed 0.8 μCi of I-125 or 1.4 μCi of I-131. The appropriate proportionate amount[5] of a mixture of these nuclides should be used as a guide when both I-125 and I-131 are present; and

(3) The working conditions during the 3-month period with respect to the potential for exposure are representative of working conditions during the period in which the quarterly bioassay frequency will be employed, and there is no reasonable expectation that the criteria in regulatory positions 4.b(1) and 4.b(2) above will be exceeded.

c. After Use of Respiratory Protection Devices. Between 6 and 72 hours after respiratory protective devices, suits, hoods, or gloves are used to limit exposure as stated in regulatory position 1.e.

For individuals placed on a quarterly schedule, sampling should be randomly distributed over the quarter but should be done within one week after a procedure involving the handling of I-125 or I-131. This will provide a more representative assessment of exposure conditions.

**5. Action Points and Corresponding Actions**

a. Biweekly or More Frequent Measurements

(1) Whenever the thyroid burden at the time of measurement exceeds 0.12 μCi of I-125 or 0.04 μCi of I-131, the following actions should be taken:

(a) An investigation of the operations involved, including air and other in-plant surveys, should be carried out to determine the causes of exposure and to evaluate the potential for further exposures.

(b) If the investigation indicates that further work in the area might result in exposure of a worker to concentrations that would cause the limiting intakes established in § 20.103 of 10 CFR Part 20 to be exceeded, the licensee should restrict the worker from further exposure until the source of exposure is discovered and corrected.

(c) Corrective actions that will eliminate or lower the potential for further exposures should be implemented.

(d) A repeat bioassay should be taken within 2 weeks of the previous measurement and should be evaluated within 24 hours after measurement in order to confirm the presence of internal radioiodine and to obtain an estimate of its effective half-life for use in estimating dose commitment.

(e) Reports or notification must be provided as required by §§ 20.405, 20.408, and 20.409 of 10 CFR Part 20 or as required by conditions of the license pursuant to § 20.108 of 10 CFR Part 20.

(2) If the thyroid burden at any time exceeds 0.5 μCi of I-125 or 0.14 μCi of I-131, the following actions should be taken:

(a) Carry out all steps described in regulatory position 5.a(1).

(b) As soon as possible, refer the case to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioactive iodine from the body. This should be done within 2-3 hours after exposure when the time of exposure is known so that any prescribed thyroid blocking agent would be effective.[4]

(c) Carry out repeated measurements at approximately 1-week intervals at least until the thyroid burden is less than 0.12 μCi of I-125 or 0.04 μCi of I-131. If there is a possibility of longer-term compartments containing I-125 or I-131 that require evaluation, continue measurements as long as necessary to ensure that appreciable exposures to these other compartments do not go undetected.

b. Quarterly Measurements. Carry out actions at levels as indicated under regulatory position 5.a(1) and (2). If measurements and surveys indicate an appreciable likelihood that a worker will receive further exposures exceeding the criteria of regulatory positions 4.b(1) and 4.b(2), reinstitute biweekly or more frequent bioassays.

## D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding

[5] See Appendix B to this guide for a description and example of using this condition for mixtures.

the NRC staff's plans for using this regulatory guide.

Except in those cases in which the applicant or licensee proposes an acceptable alternative method, the staff will use the methods described herein after December 15, 1979, in evaluating the radiation protection programs of licensees who have bioassay requirements incorporated in their licenses in accordance with § 20.108 of 10 CFR Part 20.

If an applicant or licensee wishes to use the method described in this regulatory guide on or before December 15, 1979, the pertinent portions of the application or the licensee's performance will be evaluated on the basis of this guide.

Table 1

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS NECESSARY

| Types of Operation | Activity Handled in Unsealed Form Making Bioassay Necessary* | |
|---|---|---|
| | Volatile or Dispersible* | Bound to Nonvolatile Agent* |
| Processes in open room or bench, with possible escape of iodine from process vessels | 1 mCi | 10 mCi |
| Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability | 10 mCi | 100 mCi |
| Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage | 100 mCi | 1000 mCi |

*Quantities may be considered the cumulative amount in process handled by a worker during a 3-month period; e.g., the total quantity introduced into a chemical or physical process over a 3-month period, or on one or more occasions in that period, by opening stock reagent containers from which radioactive iodine may escape. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that I-125 or I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 mCi/mg of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in nonfree form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). However, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-hand column may then be applicable. In those laboratories working only with I-125 in radioimmunassay (RIA) kits, the quantities of I-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column. In field operations, where reagent containers are opened outdoors for simple operations such as pouring liquid solutions, the above table does not apply; bioassay should be performed whenever an individual employee handles in open form (e.g., an open bottle or container) more than 50 mCi at any one time.

Operations involving the routine use of I-125 or I-131 in an open room or bench should be discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1 mCi of I-125 or I-131 should be opened at least initially within hoods having adequate face velocities of 0.5 m/sec or more.

## APPENDIX A

## SUGGESTED REFERENCES TO ASSIST IN ESTABLISHING A BIOASSAY PROGRAM

In response to public comments, this list of publications is provided to assist the licensee in establishing measurements and administrative procedures for a bioassay program appropriate to his operations. This list is not intended to be exhaustive and does not replace the need for professional assistance in establishing analytical procedures or services.


1. American National Standard, ANSI N44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom," American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018, approved August 24, 1973.

2. R. C. Brown, "$^{125}$I Ingestions in Research Personnel," Operational Health Physics, pp. 276-278, 1976, proceedings of the Ninth Midyear Topical Symposium of the Health Physics Society, Denver, Colorado, February 1976 (P. L. Carson, W. R. Hendee, and D. C. Hunt, Eds., Central Rocky Mountain Chapter, Health Physics Society, P.O. Box 3229, Boulder, Colorado 80303, $15).

3. E. J. Browning, K. Banerjee, and W. E. Reisinger, Jr., "Airborne Concentration of I-131 in a Nuclear Medicine Laboratory," J. Nucl. Med., vol. 19, pp. 1078-1081, 1978.

4. J. G. Dare and A. H. Deutchman, "The Decay Scheme of Iodine-125 and Its Relationship to Iodine Bioassay," op. cit., Ref. 2, pp. 250-254.

5. B. C. Fasiska, "Radiation Safety Procedures and Contamination Control Practices Involved in High Level I-131 Thyroid Therapy Cases," op. cit., Ref. 2, pp. 287-291.

6. A. Gavron and Y. Feige, "Dose Distribution and Maximum Permissible Burden of $^{125}$I in the Thyroid Gland," Health Physics, vol. 23, pp. 491-499, 1972.

7. B. Y. Howard, "Safe Handling of Radioiodinated Solutions," op. cit., Ref. 2, pp. 247-249.

8. ICRP Publication 10, "Report of Committee IV on Evaluation of Radiation Doses to Body Tissues from Internal Contamination Due to Occupational Exposure," Recommendations of the International Commission on Radiological Protection, Pergamon Press, Oxford, p. 17, 1968.

9. ICRP Publication 10A, "The Assessment of Internal Contamination Resulting from Recurrent or Prolonged Uptakes," Recommendations of the International Commission on Radiological Protection, Pergamon Press, Oxford, 1969.

10. A. L. Orvis, "What Is a 'Reportable' Thyroid Burden?" op. cit., Ref. 2., pp. 268-271.

11. P. Plato, A. P. Jacobson, and S. Homan, "In Vivo Thyroid Monitoring for Iodine-131 in the Environment," Int. J. Applied Radiat. and Isotopes, vol. 27, pp. 539-545, 1976.

12. Radiological Protection Bulletin 25, "Safe Working with Iodine-125," National Radiological Protection Board, Harwell, Didcot, Oxon, England, pp. 19-20, 1978.

13. R. P. Rossi, J. Ovadia, K. Renk, A. S. Johnston, and S. Pinsky, "Radiation Safety Considerations in the Management of Patients Receiving Therapeutic Doses of $^{131}$I," op. cit., Ref. 2, pp. 279-286.

14. C. T. Schmidt, "Thyroid Dosimetry of $^{125}$I and an Instrumental Bioassay Procedure," Program and Abstracts: Twenty-Third Annual Conf. on Bioassay, Environmental, and Analytical Chemistry, IDO-12083, Sept. 15, 16, 1977.

15. A. Taylor, J. W. Verba, N. P. Alazraki, and W. C. McCutchen, "Monitoring of I-125 Contamination Using a Portable Scintillation Camera," J. Nucl. Med., vol. 19, pp. 431-432, 1978.

16. Technical Reports Series No. 148, "Control of Iodine in the Nuclear Industry," International Atomic Energy Agency, Vienna, 1973.

## APPENDIX B

## CALCULATION OF ACTION LEVELS FOR MIXTURES OF I-125 AND I-131

### B.1 Controlling Instantaneous Thyroid Burdens

Regulatory position 4.b(1) is based on controlling the instantaneous amount in the thyroid and is taken as 25% of the maximum permissible organ burden (MPOB) of I-125 or I-131 that would give a dose rate of 0.6 rem/week if continuously present in the thyroid. If a mixture of both nuclides is present in the thyroid and X is the fractional activity that is I-125, a 3-month interval may be resumed when the total activity of I-125 and I-131 is below

$$0.12X + 0.04(1 - X)$$

Example

If the measurements of I-125 and I-131 in a worker's thyroid are 0.10 μCi of I-125 and 0.05 μCi of I-131, the fractional I-125 activity is

$$X = 0.10/(0.10 + 0.05) = 0.667$$

Then

$$0.12X + 0.04(1 - X) = 0.12(0.667) + 0.04(0.33) = 0.0932$$

$$\text{Total} = 0.10 + 0.05 = 0.15\ \mu\text{Ci}$$

Thus, in this case, the worker involved should remain on the biweekly (or more frequent) schedule and should not be put on the quarterly frequency.

### B.2 Controlling Total Intakes

Regulatory position 4.b(2) is based on controlling total intakes[6] during a quarterly period when air concentration data are available to assess the potential exposure of the worker either to random single intakes or to variable or constant continuous exposures. The quantities of 0.8 μCi of I-125 and 1.4 μCi of I-131 were obtained by calculating 25% of the total quarterly intakes of 3.2 μCi of I-125 or 5.7 μCi of I-131 (see footnote 3) that would be inhaled when breathing a total of $6.3 \times 10^8$ ml per quarter working at the standard man breathing rate for 40 hours per week for 13 weeks.

Example

If the average quarterly concentrations estimated from air sampled in a worker's breathing zone are $3 \times 10^{-9}$ μCi/ml for I-125 and $5 \times 10^{-9}$ μCi/ml for I-131, the total quarterly intakes are:

$$3 \times 10^{-9} \times 6.3 \times 10^8 = 1.89\ \mu\text{Ci I-125}$$

$$5 \times 10^{-9} \times 6.3 \times 10^8 = 3.15\ \mu\text{Ci I-131}$$

$$\text{Total} = 5.04\ \mu\text{Ci}$$

Also, X, the proportion of I-125, is 1.89/5.04 = 0.375

Thus the control level for maintaining biweekly or more frequent bioassay checks is:

$$0.8X + 1.4(1 - X) = 0.8(0.375) + 1.4(1 - 0.375)$$

Total = 1.18 μCi for this mixture.

Since the intake of 5.04 μCi is greater than 1.18, this employee should stay on the more frequent bioassay schedule.

Note: The numbers of significant digits carried in the above calculations do not imply any given degree of accuracy of measurement. Enough digits are carried to allow following the arithmetic for purposes of the examples.

[6] The limiting total quarterly intakes are in different proportions for I-125 and I-131 than are the MPOBs. This difference is a result of the fact that permissible concentrations are inversely proportional to effective half-lives whereas an MPOB is calculated assuming a constant burden in the organ of concern that is maintained by continuous intake of activity balanced by an equal rate of elimination from the organ.

July 1988

U.S. NUCLEAR REGULATORY COMMISSION

# REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

## REGULATORY GUIDE 8.32
## (Task OP 713-4)

# CRITERIA FOR ESTABLISHING A TRITIUM BIOASSAY PROGRAM

## 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 (NRC) may incorporate into a license provisions requiring a specific program of bioassay measurements as necessary or desirable to aid in determining the extent of an individual's exposure to concentrations of radioactive material.

This guide provides NRC staff guidance on:

1. The conditions under which the NRC staff will consider the need for license conditions related to tritium bioassays under § 20.108 of 10 CFR Part 20.

2. The scope, types, and frequency of tritium bioassay programs conducted by licensees for the purpose of demonstrating compliance with applicable provisions of 10 CFR Part 20 or for satisfying license conditions imposed under § 20.108. However, if this guide differs from the requirements of any existing license condition, the licensee should conform to such requirements until the license is amended in accordance with the Commission's regulations.

This guide provides criteria acceptable to the NRC staff for developing and implementing a bioassay program for any licensee handling or processing tritium[1] either as pure gas or in various chemical compounds. It further provides guidance to such licensees on selecting workers who should participate in a program to detect and measure possible internal radiation exposure. This guide is programmatic in nature and does not deal with measurement techniques and procedures.[2]

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 20, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 20 have been cleared under OMB Clearance No. 3150-0014.

## B. DISCUSSION

The topics treated in this guide include determinations of (1) whether bioassay should be performed, (2) frequencies of bioassay, (3) who should participate, (4) the actions to take based on bioassay results, and (5) the activity levels that should initiate such actions.

The information and references that were used in developing this guidance are summarized in NUREG-0938, "Information for Establishing Bioassay Measurements and Evaluations of Tritium Exposure."[3] NUREG-0938 also contains information that may be useful to applicants and licensees in planning and conducting bioassay programs for tritium.

The triggering concentrations given in Table 1 of this guide notwithstanding, licensees are not exempt from the air sampling and bioassay requirements of 10 CFR Part 20; particular attention should be given to paragraphs 20.103(a)(3) and 20.103(c)(2). Paragraph 20.103(a)(3) requires licensees to measure radioactivity concentrations in the air and, as appropriate, to use bioassay measurements for the timely detection and assessment of individual intakes of radioactivity. Paragraph 20.103(c)(2) requires licensees to provide bioassays as appropriate to evaluate actual exposures when the licensee wishes to make allowance for the use of respiratory protection equipment in estimating exposures of individuals to airborne radioactive material. The "appropriateness" of conducting bioassays to comply with paragraphs 20.103(a)(3) and (c)(2) must be judged on a case-by-case basis. For example, if the Table 1 concentration criteria are routinely met, but there are unexpectedly high air sampling results, bioassays may be "appropriate" in order to verify and assure that regulatory intake limits have not been exceeded.

[1]Tritium, an isotope of hydrogen, has a mass number of 3 (2 neutrons, 1 proton). Tritium may be symbolized or represented in the literature by the standard scientific symbol $^3H$ or by other symbols adopted for convenience in publication such as hydrogen-3, H-3, or T.

[2]Sections 8 through 11 of ANSI N13.14-1983, "American National Standard for Dosimetry—Internal Dosimetry Programs for Tritium Exposure—Minimum Requirements," contain some useful information on procedural aspects of bioassay programs. ANSI N13.14-1983 is available from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

[3]NUREG-0938 is available from The Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082; or from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

## Table 1

## ACTIVITY LEVELS OR CONCENTRATIONS ABOVE WHICH TRITIUM BIOASSAY PROGRAMS SHOULD BE PROVIDED

| Types of Operation[a] | HTO[b] and Other Tritiated Compounds (Including Nucleotide Precursors) | Tritium (HT or $T_2$)[c] Gas in Sealed Process Vessels[d] | HTO Mixed with More Than 10 kg of Inert $H_2O$ (e.g., in Reactor Coolant)[e] |
|---|---|---|---|
| Processes in open room or bench with possible escape of tritium from process vessels | 0.1 Ci | 100 Ci | 0.01 Ci/kg |
| Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability | 1 Ci | 1,000 Ci | 0.1 Ci/kg |
| Processes carried out within gloveboxes that are ordinarily closed but with possible release of tritium from process vessels and occasional exposure to contaminated box and leakage | 10 Ci | 10,000 Ci | 1 Ci/kg |

[a]Quantities (< 10 kg) of substances containing tritium that are present during operations may be considered to be either the amount processed by an individual at any one time (when accidental intake is more likely) or the amount of activity that entered into the process (throughput) during any one month (when routine handling of repeated batches is the more likely source of exposure).

[b]HTO is a symbol for a water molecule in which a tritium atom (T) is present in place of a normal hydrogen atom (H).

[c]A molecule of hydrogen gas contains two hydrogen atoms. Either one of these atoms may be replaced with T to form HT, or two T atoms may combine to form $T_2$ gas.

[d]This assumes that adequate air monitoring has established that there is no tritium leakage or that no significant amount of tritium gas can be converted to HTO before intake.

[e]This column is applicable in place of the previous two columns in cases where tritium can be identified at measurable concentrations in large amounts of water or other substances, such as at nuclear power plants.

For the user's convenience, the following terms are presented with their definitions as used in this guide:

**Bioassay**—The determination of the kind, quantity or concentration, and location of radioactive material in the human body by direct (in vivo) measurement or by analysis (in vitro) of materials excreted or removed from the body. Only in vitro analysis of urine (or, if more convenient, another representative body fluid) is applicable to tritium or its compounds.

**Intake**—The total quantity of radioactive material entering the body.

**Uptake**—The total quantity of radioactive material retained in the body (i.e., not immediately exhaled) after an intake.

## C. REGULATORY POSITION

### 1. CONDITIONS UNDER WHICH BIOASSAY IS NECESSARY

**1.1.** Routine bioassay is necessary when quantities of tritium processed by an individual at any one time or the total amounts processed per month exceed those shown in Table 1 for each form of tritium.

**1.2.** For workers in nuclear reactor facilities, urine bioassay should be performed when the concentrations of tritium in the reactor coolant water exceed those shown in the right-hand column of Table 1. The lowest value in Table 1, 0.01 Ci/kg of coolant, should be used to initiate a bioassay program whenever employees are exposed to the air in a room or area where more than 10 kg of water containing this or greater concentration or a total of more than 0.1 Ci of tritium is in contact with the air (such as a storage pool). If exposure to water containing a concentration of tritium greater than or equal to 1 Ci/kg is expected, such as when leakages occur, a bioassay program should be initiated because significant intakes, both by inhalation and by absorption of water vapor through the skin, can occur when individuals are exposed to tritium at these concentrations.

**1.3.** Bioassays should also be performed when an employee can come into skin contact with, ingest, or absorb into the body through cuts, abrasions, or accidental (hypodermic) injection, water or any other substance with concentrations of tritium greater than or equal to 0.01 mCi/kg (0.01 $\mu$Ci/cc) such as may be common in laboratory applications.

## 2. PARTICIPATION

All workers involved in the processing of tritium under conditions specified in Regulatory Position 1 or in the environs of the process should participate in the bioassay program.

## 3. TYPES OF BIOASSAY THAT SHOULD BE PERFORMED

### 3.1 Baseline (Preemployment or Preoperational)

A baseline bioassay of each worker should be conducted before that worker begins working with tritium in amounts that would require initiation of a bioassay program as specified in Regulatory Position 1.

### 3.2 Routine

Regular bioassays should be conducted to monitor routine operations at frequencies specified in Regulatory Position 4.

### 3.3 Postoperational and with Termination Physical Examination

A bioassay should be performed within one month after the last possible exposure to tritium, when operations are being discontinued, or when the worker is terminating activities with potential exposure as indicated by the criteria in Table 1.

### 3.4 Diagnostic

A followup bioassay should be performed as soon as possible but not later than one week after any sample exceeding levels given as action points in Regulatory Position 5 in order to confirm the initial results and, in the case of a single intake, to allow an estimate of the effective half-life of the tritium in the body. If the initial sample or other data indicates a possible exposure high enough to warrant immediate medical attention, complete and immediate followup should be conducted as described in Regulatory Position 5.1.3.

## 4. FREQUENCY OF SAMPLING

### 4.1 Initial Routine

A bioassay sample should be taken within 24 hours, if possible, but not later than 72 hours following entry of an individual into an area where operations require bioassay according to Regulatory Position 1. Samples should then be taken every two weeks or more frequently as long as the individual is working with tritium. When work with tritium is on an infrequent basis (less frequently than every two weeks), bioassay should be performed within ten days of the end of the work period during which tritium was handled. Samples should not be collected until two hours after termination of the potential exposure in order that bladder contents will have had time to equilibrate with other body water.

### 4.2 After Three Months

A sampling frequency selected in accordance with Regulatory Position 4.1 may be changed to quarterly if, after three months, the following three conditions are met:

**4.2.1** The average urinary tritium concentration in specimens obtained from the worker during the three-month period does not exceed 3 $\mu$Ci/L,

**4.2.2.** If measurements of the concentration of tritium in air are required as a condition of the license, the quarterly average concentration ($\mu$Ci/mL) to which workers are exposed multiplied by the factor $6.3 \times 10^8$ mL does not exceed 0.8 mCi, and

**4.2.3.** The working conditions during the three-month period, with respect to the potential for tritium exposure, are representative of working conditions during the period in which a quarterly urinalysis frequency is employed, and there is no reasonable expectation that the criteria given in items 4.2.1 and 4.2.2 above will be exceeded.

## 5. ACTION POINTS AND CORRESPONDING ACTIONS

### 5.1 Biweekly or More Frequent Sampling

**5.1.1.** Whenever the intake of tritium within any 40-hour work period exceeds the amount that would be taken into the body from uniform exposure for 40 hours at the air concentration ($5 \times 10^{-6}$ $\mu$Ci/mL) specified in Table 1, Column 1, of Appendix B to 10 CFR Part 20,[4] the licensee is required to make evaluations, take necessary corrective actions, and maintain records as specified in paragraph 20.103(b)(2) of 10 CFR Part 20.

**5.1.2.** If urinary excretion concentrations exceed 5 $\mu$Ci/L but are less than 50 $\mu$Ci/L, the following course of action should be taken:

1. An investigation of the operations involved, including surveys and monitoring of air and surface contamination, should be carried out to determine the causes of the intake, and an evaluation of the potential for further larger intakes or of the possible involvement of other employees should be performed.

2. Any reasonable corrective actions that the investigation indicates may lower the potential for further exposures should be implemented.

3. A repeat urine sample should be taken within one week of the previous sample and should be evaluated within a

[4]Multiplying the concentration given in Appendix B, $5 \times 10^{-6}$ $\mu$Ci/mL, by $6.3 \times 10^8$ mL gives the corresponding quarterly intake limit of tritium by inhalation. In the case of inhaled HTO, which mixes instantly with other water molecules after entering body fluids, the intake may be assumed equal to uptake. The uptake of tritium (as HTO) by absorption through the skin is assumed equal to the uptake by inhalation unless the form of tritium in the air can be demonstrated to have lower uptakes. The total uptake, including skin absorption, would be assumed to be about 6.3 mCi, which delivers a dose commitment of about 1.25 rems to standard man (using the quality factor Q=1.7). A 40-hour occupational exposure at a concentration of $5 \times 10^{-6}$ $\mu$Ci/mL would thus result in an intake of 6.3/13=0.48 mCi and a dose commitment of about 0.1 rem. An acute intake (in less than one day) of 0.48 mCi would result in an initial body water concentration of about 11 $\mu$Ci/L. (The use of Q=1.7 in this example follows the practice used in developing concentration limits for the current 10 CFR Part 20. Changes in recommendations of various committees and a review of quality factor determinations reported in the literature are presented in NUREG-0938.)

week after collection. Internal dose commitments should be estimated using at least these two urine sample evaluations and other survey data, including the probable times of the intake of tritium.

4. Any evidence indicating that further work in the area might result in an employee receiving a dose commitment in excess of the limits established in § 20.101 should serve as cause to remove the employee from work in this operation until the source of exposure is discovered and corrected.

5. Reports or notifications must be provided as required by §§ 20.405, 20.408, and 20.409 of 10 CFR Part 20 or as required by conditions of the license pursuant to § 20.108 of 10 CFR Part 20.

**5.1.3.** If urinary excretion concentrations exceed 50 μCi/L, the following course of action should be taken:

1. Carry out all steps in Regulatory Position 5.1.2.

2. If the projected dose commitment exceeds levels for the whole body as provided in § 20.403 of 10 CFR Part 20, notify the NRC as appropriate.

3. Refer the case to appropriate medical and health physics consultants for recommendations regarding the need for immediate therapeutic procedures that may be carried out to accelerate removal of tritium from the body.

4. Carry out repeated sampling at approximately one-week intervals at least until urine samples show concentrations less than 5 μCi/L. If there is a possibility of long-term organic compartments of tritium that require evaluation (see NUREG-0938), continue sampling as long as necessary to ensure that appreciable exposures to these other compartments do not go undetected and to provide estimates of total dose commitments.

**5.2 Quarterly Sampling**

Carry out the actions called for when any of the action levels indicated in Regulatory Position 5.1 are exceeded. In addition, institute biweekly (or more frequent) sampling for at least the next six-month period, even when urinary concentrations fall below 5 μCi/L.

## D. IMPLEMENTATION

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

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, or cases in which different requirements are imposed by any existing license condition, the methods described in this guide will be used in evaluating the need for license conditions related to tritium bioassay programs and in evaluating the radiation protection programs of licensees that have bioassay requirements incorporated in their licenses in accordance with § 20.108 of 10 CFR Part 20. This guide will also be used in evaluating changes to existing bioassay programs that may be requested by licensees.

## BIBLIOGRAPHY


American National Standards Institute, "American National Standard for Dosimetry—Internal Dosimetry Programs for Tritium Exposure—Minimum Requirements," ANSI N13.14-1983,[1] 1983.

Brodsky, A., "Information for Establishing Bioassay Measurements and Evaluations of Tritium Exposure," NUREG-0938,[2] U.S. Nuclear Regulatory Commission, Washington, DC, 1983.

Duijsings, J. H., et al., "Internal Contamination of Radiological Workers by Tritium Compounds at Two Universities in the Netherlands," *Health Physics*, Vol. 46, pp. 665-669, 1984.

International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP-30,[3] Part 1, 1979.

Johnson, J. R., "Frequency of Bioassay Monitoring for Internal Contamination and Its Relationship to Sensitivity and Accuracy Requirements," *Health Physics*, Vol. 46, p. 715, 1984.

Kinslow, R., J. J. Moschella, and C. N. Cawley, "A Model of Urinary Tritium Following Multiple Contaminations," *Health Physics*, Vol. 46, pp. 1154-1155, 1984.

Minister of National Health and Welfare of Canada, "General Guidelines for Bioassay Programs," Bioassay Guideline 1, Report 80-EHD-56,[4] 1980.

Minister of National Health and Welfare of Canada, "Bioassay Guideline 2, Guidelines for Tritium Bioassay," Report 83-EHD-87,[4] 1987.

Myers, D. K., and J. R. Johnson, "Estimating the Biological Hazards of Tritium," *Health Physics*, Vol. 46, p. 715, 1984.

Smith, L. R., et al., "Human Execretion Patterns Following Occupational Uptake of $^{3}H$, $^{14}C$, and $^{35}S$-Labelled Compounds," *Health Physics*, Vol. 44, pp. 221-234, 1983.


[1]Copies of ANSI standards may be purchased from The American National Standards Institute, 1430 Broadway, New York, NY 10018.

[2]Copies may be purchased from the U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082.

[3]Copies may be purchased from Pergamon Press, Inc., Maxwell House, Elmsford, NY 10523.

[4]Copies may be obtained from the Minister of National Health and Welfare of Canada, Radiation Protection Bureau, Brookfield Road, Ottawa, Ontario K1A IC1, Canada.

## VALUE/IMPACT STATEMENT

A draft value/impact statement was published with Draft Regulatory Guide OP 713-4 when the draft guide was published for public comment in June 1983. No changes were necessary, so a separate value/impact statement for the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. under Task OP 713-4.