

RADIATION SAFETY RULES and REGULATIONS

FOR THE HUMAN USE OF RADIOACTIVE MATERIALS

**AT NYU MEDICAL CENTER
& BELLEVUE HOSPITAL CENTER**

These Rules & Regulations are issued by the Radiation Safety Office
NYU Medical Center,
550 First Avenue, New York, NY 10016
Room MSBG58

(212) 263-6888.

**This manual has been approved by the Radiation Safety Committees of NYU
Medical Center
and Bellevue Hospital Center.**

**For further information contact:
The Radiation Safety Office
NYU Medical Center,
550 First Avenue, New York, NY 10016
Room MSBG58
(212) 263-6888.**

Introduction

Radiation work is subject to very stringent regulation, and each employee and supervisor who is involved in such work should be familiar with the proper safety procedures. The rules and regulations in this document have been devised to reconcile the need to use radiation sources in clinical and research programs with the requirements of the regulatory agencies.

Please consult the staff of the Radiation Safety Department if there is any doubt about proper procedures. We always welcome the opportunity to make a constructive contribution to the safe use of sources of ionizing radiation.

*S.R. Wagner, MS, DABR, DABMP
Radiation Safety Officer
Director of Radiation Safety
Adjunct Assistant Professor of Radiology
New York University
New York University Medical Center
Bellevue Hospital Center*

**The term "RSO" "RSC" and "MIC" are used throughout this document to refer to the
Radiation Safety Officer, the Radiation Safety Committee, and the Medical Isotopes Committee,
respectively.**

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Applicable External Regulations

The possession and use of sources of ionizing radiation within New York City are subject to the regulations of the NYC Department of Health, Office of Radiological Health, published under Article 175 of the City Health Code (*Health Code*). The City acts in part for New York State, which is an Agreement State, and thus assumes many of the responsibilities of the Nuclear Regulatory Commission (NRC) including the issuance of licenses. Radioactive materials used for diagnosis, treatment or research in humans also fall under the jurisdiction of the Food and Drug Administration (FDA). Other State and Federal regulations apply to specific issues such as the discharge of radioactive materials to the environment and the transportation of radioactive materials, and to the use of sources outside the City. The RSO can advise on specific regulatory issues.

In accordance with Article 175, a copy of Article 175, all radioactive materials licenses and associated documents, the radiation installation permits, the operating procedures, records of personnel monitoring, any notices of violation involving radiological working conditions, and any proposed imposition of civil penalty or order issued pursuant to the provisions of the Health Code, are all available for inspection in the Radiation Safety Office during normal working hours, or by arrangement.

Application of these Internal Rules and Regulations

These internal rules and regulations apply specifically to the *human use* of radioactive materials (administration or application of radioactive materials to humans for routine or research purposes) at NYU Medical Center in New York City and in Bellevue Hospital. Approval of *research use* in humans is coordinated with the IBRA review through the Grants Office. Other rules and regulations apply to non-human use (in vitro or animal work) involving radioactive materials, and to work involving machine sources of radiation, at these locations and at the Nelson Institute in Sterling Forest, and at all other facilities operated by NYU. Inquiries should be directed to the RSO at the location shown on page 1. Issues which relate to the use of other hazardous materials, or to general safety concerns, should be addressed to the Environmental Services Department of NYU, NYU Medical Center, or Bellevue Hospital Center, as appropriate.

Licenses

Use of radioactive material (radioisotopes) at specific locations within NYU Medical Center in New York City, and in Bellevue Hospital Center, is permitted under licenses issued by the NYC Department of Health, and administered by the RSO on behalf of the RSC. Use of material outside these locations is not authorized by these licenses. (See section C3).

Radiation Safety Committees, Officer, Department, and Office

The Medical Boards of NYU Medical Center and Bellevue Hospital Center and the Management of these Centers have each established Radiation Safety Committees which assume the detailed responsibilities of the two institutions as laid down in Article 175, and in the licenses. These Committees have agreed to establish a common Radiation Safety Program within the two institutions. Detailed responsibilities for authorizing human use of radioactive materials under this program have been assigned to the Medical Isotopes Subcommittee of the Radiation Safety Committee. The Radiation Safety Program is administered by the Radiation Safety Officer with the assistance of the staff of the Radiation Safety Department. The main administrative office of the Department (the Radiation Safety Office) is based at the location shown on page 1. Satellite offices and other support services are maintained at other locations within NYU, NYU Medical Center and Bellevue Hospital Center.

A. AUTHORIZATION

A1. Authorization Requirements for Human Use of Radioactive Materials:

Radioactive material may not be used for human use purposes unless the responsible physician and the conditions of use have been specifically approved by the Medical Isotopes Subcommittee (MIC) of the RSC. *There is no exception to this requirement.* Authorization will only be granted to a physician who has documented training which meets criteria established in the Health Code. An authorized physician may then supervise authorized work done by others, as permitted by law. The RSC and MIC will report to the Medical Boards of NYU Medical Center and Bellevue Hospital Center. The RSO will advise on current training requirements.

A2. Applications for Authorization:

Applications for routine use are made through the RSO. Research applications which involve the human use of radioactive materials are referred to the RSO by the Grants Office. The RSO reviews the training, experience and laboratory facilities of the applicant, based on criteria established by the MIC, and will refer the application to the MIC for approval. In some situations the radioactive materials license must also be amended by the Health Department before authorization can be granted.

A3. Conditions:

General and specific conditions will be imposed by the MIC on the routine or research human use of radioactive materials. The RSO will provide the specific details on a case-by-case basis, and may modify them as necessary at any time to meet regulatory requirements. *Authorization is only valid at the locations covered by these regulations as discussed on page 3.*

A4. Amendments:

A written request for authorization is required before any change is made to the conditions of use, and changes may require the authorization of the MIC. Applications are made through the Radiation Safety Office. *The RSO may modify the conditions of use at any time to meet regulatory requirements.*

A5. Periodic review:

The Radiation Safety Office will initiate a review of all authorizations periodically, and at least once per year, and will provide a status report to the MIC and RSC, and thence to the Medical Board.

A6. Conditional Renewal, Suspension or Cancellation of Authorization:

The RSO may add conditions, suspend, or cancel authorization at any time based on lack of compliance with safety or regulatory requirements, subject to subsequent ratification by the MIC.

A7. Inactivation and Reactivation of Authorization:

The RSO may inactivate authorization if no material is used over an extended period. Residual materials must then be transferred to the RSO for storage or disposal, and the RSO will ensure that there is no residual contamination, and will remove signs from the facility. Requests for reactivation must be in writing and may need to be authorized by the MIC.

A8. Termination of Authorization:

A Request for termination of authorization should be made after all material has been properly disposed, and after the laboratory has been shown to be free of residual contamination. The RSO will verify that these steps are taken before the authorization is terminated, and the authorized user remains responsible until that time.

B. GENERAL CONDITIONS WHICH APPLY TO ALL AUTHORIZED USERS.**B1. Quantities of Materials Authorized.**

The quantity of each radioisotope which is authorized must be consistent with the limits of the institutional licenses, which limit the total quantity of each radioisotope that can be possessed when all quantities of that radioisotope on all premises covered by the license are combined. The maximum quantity of any radioisotope which is allowed is also limited by safety considerations including the *external hazard*, based on the potential exposure rate if the material is outside the body, the *internal hazard*, based on the potential dose from material taken into the body, and the *limits on release of the material to the atmosphere* if it is volatile. The RSO will provide specific instruction.

B2. Requirements for all facilities where radioisotopes are stored or used:

- (i) All radioisotope sources must be directly supervised or secured at all times. Facilities where sources are used or stored must be secured when not in use.
- (ii) Storage and handling facilities must be shielded to reduce the potential exposure to individuals to an acceptable level.
- (iii) A clearly identified work area must be set aside for handling radioactive materials. This must be protected by plastic backed paper or trays sufficient to contain any possible spillage.
- (iv) Appropriate fume hood or glove box facilities are required if there is a possibility of dust or vapor which could cause exposure through contamination, inhalation or ingestion.
- (v) Filters or traps may be required to prevent release to the atmosphere above the levels permitted by regulation, and to minimize such release.

B3. Special Requirements for Human Use:

All use of radioactive materials for human use purposes will be performed in compliance with all applicable regulations including those of the Health Department. [See section I].

B4. Requirements for radiation warning signs:

- (i) *Caution Radioactive Material* signs which carry the radiation warning symbol must be conspicuously displayed in each work area and at each entrance to an area where radioactive materials will be used or stored. *Required signs should not be removed from an entrance to an area until it is formally decommissioned by the RSO.*
- (ii) In situations where high exposure rates exist, the RSO may require the posting of *Caution Radiation Area* signs. These should not be used unless required.
- (iii) Equipment containing sources and containers in which radioisotopes are transported or stored must bear a durable and clearly visible *Caution Radioactive Material* label. This label should also state the quantities and kinds of radioactive materials in the containers and the date of determination. Containers which are used for short-term manipulation are exempted, but should be placed in labeled containers after use.
- (iv) All equipment or surfaces contaminated with radioactive material must be conspicuously marked with *Caution Radioactive Material* labels.
- (v) Any sink used for aqueous waste disposal must be approved and specially marked by the RSO.
- (vi) *Radiation warning signs must not be used inappropriately, and must be obliterated before empty containers, including transport boxes, are discarded.*

B5. Required Notices

An internal *Emergency Procedures Notice* and the NYC Health Department *Notice to Employees* will be posted by the RSO near areas where radioactive materials are used. Any special safety procedures which apply in an area must also be posted near that area. *These notices should not be removed unless the area is formally decommissioned by the RSO.*

B6. Requirements for Staff who use Radioactive Materials:

- (i) Initial, and annual refresher training of staff is required for all staff who frequent areas where radioisotopes are used or stored. General safety training is provided by the RSO, but job-specific (performance based) training to ensure safety and to avoid the contamination of personnel and facilities, is to be provided by each authorized user. Such training must be documented.
- (ii) Licensed nuclear medicine technologists may inject patients with radioactive materials only if they have received special training and if they have been individually approved by the Medical Board of NYU Medical Center or Bellevue Hospital Center as appropriate.

(ii) The proper use of prescribed personal monitoring devices such as film or TLD badges or ring badges is required. Staff shall also report regularly for any prescribed bioassay monitoring such as thyroid counting, and urine analysis. The RSO provides detailed instructions for the proper use of monitors, and determines when bioassay is needed.

(iii) Use of all prescribed protective measures is required. Mouth pipetting radioactive materials and eating or drinking in areas where materials are handled are all specifically prohibited. Smoking is prohibited in all Hospital facilities.

(iv) Prompt reporting to the RSO of accidental inhalation, ingestion, skin contamination or injury involving radioactive materials, as well as spills, thefts and losses, is required. The posted Emergency Procedures shall be followed when necessary. These reports are in addition to any standard reporting procedures. The RSO will determine whether a report to an external agency is required.

B7. Required Instrumentation:

Each authorized user is required to provide, or have access to, adequate instrumentation to verify the quantity of any radioactive materials administered or the calibration of sealed sources for human use. Instrumentation must also be available to evaluate radiation levels and levels of contamination, as appropriate. All instruments must be maintained in good repair and calibrated at the frequency defined by regulation. Survey instruments must be calibrated annually, or after repair or readjustment. The RSO arranges for the calibration of portable survey meters but the authorized user is responsible for providing appropriate calibration standards for fixed equipment, such as a scintillation well counters and dose calibrators.

B8. Required Records:

(i) Each authorized user is required to maintain records of the receipt, use and disposal of each shipment of radioactive materials, in a format which is acceptable to the RSO. This will include a record of checks of contamination for each package received, *performed within three hours of receipt of the package, or of the start of the workday*, whichever is later. The record should document the fate of each shipment which is received, including disposal or transfer to another user. (See section C3)

(ii) Each authorized user is required to maintain records of checks for contamination and/or survey of radiation levels as appropriate, in a format which is acceptable to the RSO. Wipe checks must be performed and recorded at least once in any week in each area where any radioisotope are routinely used, administered, or stored (unless they are in the form of sealed sources) using a technique which can detect at least 1000dpm/100cm² for beta or gamma emitters. All records should establish that the level of contamination falls below the limits listed in Appendix C. The RSO should be notified if these limits are exceeded after decontamination is completed.

(iii) All required records should be surrendered to the RSO when the authorization is terminated.

C. ACQUISITION OF RADIOACTIVE MATERIAL

Radioactive materials shall only be acquired with the specific approval of the RSO. *Gifts and transfers from other locations are not exempt from this requirement.*

C1. Purchases:

Purchase requisitions must be delivered to the Radiation Safety Office for approval. FAX, mail or hand deliveries are accepted, and will then be transmitted to the Purchasing Department. Requisitions which are sent directly to the Purchasing Department will not be processed. The RSO may also reject orders where the radioisotope or quantity is inconsistent with the authorization, if the authorization is suspended, or for any other appropriate reason.

C2. Standing or Blanket Orders:

Requests for Standing (Blanket) Orders are subject to the previous approval process. These orders allow the authorized user to obtain radioactive materials when required, within the limits of the standing order. The RSO may impose restrictions on these orders to ensure that the use of material may be tracked reliably. *Standing (blanket) orders may be canceled by the RSO if they are used to obtain materials or quantities not authorized, or if the authorized user is not in good standing for other reasons.*

C3. Exceptions will be allowed for orders of routine clinical supplies which fall within pre-determined limits as established by the RSO, but these will be subject to periodic audits.

C4. Transfers:

(i) Radioactive materials may be transferred between properly authorized users within the locations covered by these regulations, as discussed on page 3. Such transfers shall be recorded in the records of both parties to the transfer.

(ii) Radioactive materials shall not be transferred to or from other locations, including other divisions of NYU or affiliated institutions, such as the VA, HJD, and PHRI, without the specific approval of the RSO. It will usually be necessary for the RSO to obtain the formal authorization of the other institution and a copy of their license before any material is transferred. Any shipment must comply with packing and transportation requirements.

D. DISPOSAL OF RADIOACTIVE MATERIAL

It is the responsibility of each authorized user to *Minimize and Separate* radioactive waste according to half-life and other characteristics, and to avoid generation of wastes for which there is no means for disposal. Wastes which contain long half-life radioisotopes, or which are mixtures of radioactive materials and other hazardous materials, and infectious wastes, may create particularly difficult disposal problems. The quantity, and the physical, chemical, or biological form of waste products should be considered before any radioisotope work is performed. Each authorized user is required to dispose of material according to the instructions of the RSO. The disposal situation is subject to change, and the RSO should be consulted about the situation which currently applies. Each investigator should make every effort to minimize the production of large volumes or excessive activity of waste by careful planning and by staff supervision.

D1. Disposal in the sewer

Human excreta which contain radioactivity may be disposed of to the sanitary sewer without restriction. Unless specifically prohibited, each authorized user may also dispose of up to 1% (as activity) of each radioisotope actually used, in a sink in the facility, provided that all other applicable requirements are met. Disposal of more than 1% of the material used requires specific, written authorization, and is granted only in exceptional circumstances. This is because of the need to maintain institutional control and documentation.

D2. Decay of waste within the facility

Very short lived waste, such as that associated with nuclear diagnostic studies, may generally be stored in the clinical facility provided that it is secure and subsequently disposed of in accordance with institutional policies, and provided that all radioactive signs or markings are obliterated before disposal.

D3. Disposal by transfer to the RSO

The RSO provides institutional disposal facilities, and arranges for transfer of waste to external disposal facilities, where available. This service is based on the collection of waste at locations which are accessible from all parts of the complex and which are open for receipt of waste on a schedule or by appointment. Current information on the schedule, categories of waste accepted, and any associated charges can be obtained from the Radiation Safety Office. *Authorized users are responsible for separating and preparing waste according to specifications provided by the RSO, for providing accurate documentation of contents and activity in a format which is acceptable to the RSO, and for transporting waste to the collection locations.* The Radiation Safety Office will provide collection containers and detailed instructions.

E. EXPOSURE OF PERSONNEL TO IONIZING RADIATION

The upper limits to the radiation doses that personnel may receive under City, State and Federal regulations are listed in Appendix A. It is institutional policy to maintain personnel exposures *As Low As Reasonably Achievable* (ALARA). This requires that all exposures be justified and reduced to a minimum consistent with practical and economic considerations. This policy requires the active participation of all personnel, and is implemented by periodic review of the results of personnel monitoring by the RSC, and through the training programs. The aim of the policy is to keep individual radiation doses below one tenth of the regulatory limits to the extent possible, while minimizing the sum of doses to all exposed individuals, or *collective dose*.

E1. Personnel who are classed as Occupationally Exposed:

Individuals who may be exposed to radiation because of their choice of occupation are considered to be occupationally exposed, and the corresponding regulatory limits apply. They shall receive training to ensure that they have the information necessary to minimize their exposure and the exposure of others, and be monitored for exposure if appropriate. The RSO will determine whether individual monitoring is required, and the form of that monitoring.

E2. Personnel who are not classed as Occupationally Exposed:

Staff who are not classed as occupationally exposed are individuals who do not work directly with radiation sources, but who might be exposed as the result of use by others. Staff in this category should receive general information about the use of sources, and the protective measures which are designed to ensure safety. Such training is provided by the RSO to the extent possible, and by request. Protection is generally assured by restrictions placed over the use of sources, by limiting potentially high levels of exposure to *controlled areas* and by restricting access to such areas, and by the design of facilities. It is confirmed by facility monitoring and survey data. Individual monitoring is not normally required, except where this is useful in establishing safety on a survey basis. The RSO should be consulted about specific situations.

E3. Pregnant Employees:

There are specific regulatory limits on the exposure of the unborn. Pregnant employees who are classed as occupationally exposed are encouraged to make an appointment with the RSO and to declare their pregnancy in confidence if necessary. The RSO will provide counseling regarding the work situation and advice on minimizing exposure to the embryo and fetus. Additional monitoring may also be provided.

E4. Personnel Monitoring:

The RSO determines whether personnel monitoring is necessary based on the potential for significant exposure, and taking into account the specific sources involved and the frequency with which they are used. Where monitoring is prescribed, each individual is required to use the monitors provided according to the instructions of the RSO. The following types of monitoring may be provided, as appropriate:

- (i) Film or TLD Badges - for monitoring body exposure for those working in the presence of significant quantities of energetic beta or gamma emitters. Additional monitors may be provided for specific regions of the body, or in the case of pregnancy.
- (ii) Finger (ring) dosimeters - for monitoring hand exposure for those handling significant quantities of energetic beta or gamma emitters on a frequent basis.
- (iii) Bioassay, such as urine analysis or whole-body counting - where there is significant potential for intake of radioactive material, or after an accident where appropriate.
- (iv) Thyroid Counting, on a regular basis for those who use significant quantities of radioiodine, such as for therapeutic purposes.

F. OVERSIGHT OF RADIATION SAFETY

F1. Periodic Inspections by the New York City Office of Radiological Health:

The New York City Health Department may conduct inspections at any time without prior notice. All inspection reports are reported to the Administration and considered by the RSC. This process of review may result in remedial actions. The RSO will advise individual authorized users of any action that is necessary on their part.

F2. Other Agency Inspections:

Several other agencies have jurisdiction over specific issues. The RSO should be contacted if an issue related to radiation safety arises during any inspection or accreditation procedure.

F3. Continuous Review by the RSO:

The RSO reviews all aspects of the Radiation Safety Program on a continuous basis using the data maintained in the Radiation Safety Office and other sources, and arranges that all laboratories are visited on a regular basis by the Radiation Safety Department staff. This process of review may result in remedial actions, or suspension or termination of an authorization in extreme situations, subject to ratification by the MIC and RSC.

F4. Periodic Review by the MIC and RSC:

The RSO presents the results of staff review to the MIC and RSC on a quarterly basis. The RSC may also perform independent audits of the Radiation Safety Program.

F5. Review by the Administration:

The reports of agency inspections are addressed to the institutional Administration, which also receives periodic reports from the RSO, and the reports of the MIC and RSC.

G. SUPPORT SERVICES PROVIDED BY THE RADIATION SAFETY DEPARTMENT

G1. Information:

The RSO maintains a library of regulatory codes including Article 175 of the Health Code, advisory publications, and general texts and will advise on any radiation safety issue.

G2. Instrument Calibration:

A calibration service for portable survey meters is provided for instruments which are registered with the Radiation Safety Office. The Office maintains the required records.

G3. Personnel Monitoring:

Personnel monitoring for external and internal sources of exposure, as appropriate, is provided. The Radiation Safety Office maintains the required records, which are available for inspection in the Office. Annual and termination reports are also provided. The RSO reviews the reports of monitoring on a continuous basis and takes remedial action.

G4. Training Resources:

Training classes are provided on a regular schedule. The Radiation Safety Office also provides printed materials to assist with the on-the-job training which each authorized user is required to provide. A video training library is also maintained. Customized training may also be provided, on request.

G5. Purchase Inventory:

The Radiation Safety Office tracks all purchases of radioisotopes for NYU, NYU Medical Center (including the Nelson Institute), and Bellevue Hospital Center, and maintains the associated records. It may be possible to locate other users of a specific compound through this database, on request.

G6. Disposal:

The Radiation Safety Department provides institutional facilities for waste disposal and the associated records and will provide advice on this issue.

G7. Facility design and review:

The Radiation Safety Department performs monitoring and surveys, and reviews shielding and laboratory designs, ventilation, fume hoods and filtration systems as necessary to ensure radiation safety.

G8. Machine Sources of Radiation:

The Radiation Safety Office tracks the use of all machine sources of ionizing radiation and participates in the technical quality control program for all services which use diagnostic X-ray equipment.

G9. Human use of Radiation Sources:

The Radiation Safety Office tracks the use of radiation sources for diagnosis and therapy, and provides associated staff protection services.

G10. Research which involves Radiation Sources:

The RSO reviews all research protocols which involve the use of radioactive materials in coordination with the Grants Office. Protocols which involve the use of radioactive materials in human investigations are reviewed in coordination with the IBRA review process, and referred to the Medical Isotope Subcommittee of the RSC.

H. ACCIDENTS AND EMERGENCIES INVOLVING RADIATION SOURCES

H1. Accidents and Emergencies:

The *Emergency Procedures Notice* which is posted by the RSO in each area where radioisotopes are used should be followed for any accident or emergency situation which involves radioactive materials. All such situations are to be promptly reported to the Radiation Safety Office, in addition to routine reporting requirements. The Radiation Safety Office will initiate the radiation emergency response procedure during normal office hours. At other times, response is initiated through the telephone supervisor of NYU Medical Center. Instructions are also provided as a recorded message at the Radiation Safety Office telephone number listed on page 1. The RSO will determine whether a report to an external agency is required.

H2. Thefts and Loss:

The theft or loss of radioactive material is to be promptly reported to the RSO in addition to standard reporting procedures. The RSO will determine whether a report to an external agency is required.

I. SPECIAL REQUIREMENTS FOR HUMAN USE OF RADIOACTIVE MATERIALS

I1. Compliance with City and State Requirements:

I2. Quality Assurance Programs;

The quality assurance/quality control requirements of Article 175 part 07 of the Health Code will be followed, including those provisions which may require an external audit of the program.

I3. Misadministration Reporting.

If Medical Misadministration as defined in Article 175 part 02 occurs, the RSO will determine whether a report to any external agency is required. The quality misadministration reporting requirements of Article 175 part 07 of the Health Code will then be followed in addition to any other misadministration reporting that may be required as part of standard procedure.

I4. Hospitalization Requirements.

Patients will be admitted to single rooms with private sanitary facilities where necessary to satisfy the requirements of Article 175 part 103 of the Health Code, and will remain there until the RSO or designee has determined that the patient may be released from isolation or from the hospital based on an evaluation of the potential for subsequent exposure of other individuals.

I5. Use of approved radiopharmaceuticals

(ii) Radiopharmaceuticals and brachytherapy devices which are acquired for routine human use must be approved under *FDA regulations*, and must be used in a manner which is consistent with these regulations.

(iii) Investigational radiopharmaceuticals and devices are normally subject to *FDA IND regulations*, but very small quantities of material may be exempt if used for *metabolic tracer studies* if this has been specifically approved by the MIC acting as an Radioactive Drug Research Committee (RDRC) with FDA approval. The RSO will determine whether such approval may be made by the MIC/RDRC.