Licensing Guidance for Research and Development Laboratories

This supplement is intended for use by applicants desiring to obtain licensure, amendments or renewal for authorization to possess sealed and unsealed radioactive material.
NOTE: Please submit all hard copy correspondence in duplicate.

New and Renewal Applications for a Radioactive Material License

Include the following information with a letter requesting a new or renewal of radioactive materials license:

1. Include a fully completed "Application for Radioactive Material License", form (RH 2050), executed by an individual with financial and legal responsibility for the company accompanied by appropriate fees. If more space is required, the information specified on form RH 2050 may be provided on attachments thereto. Further guidance is provided in the appendices that follow. Form RH2050 may be obtained online from the department's website at: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/rh2050.pdf
2. All information requested in Appendices A-M of this checklist.

Amendment Applications to a Radioactive Material License

For amendment requests, please provide a letter from the Radiation Safety Officer or an individual with financial and legal responsibility for the company requesting the required changes. Also include the information requested in the appropriate appendices of this checklist. Amendments to a Radioactive Material License may include, but are not limited to, changes to any of the items listed below:

1. Company Ownership
2. Mailing / Billing Address
3. Radioactive Material Authorization
4. Personnel
5. Storage and Use location(s)
6. Radiation Safety Program
7. Termination of Radioactive Materials License

Appendix A: Entity Information

1. Entity
    a. Name of the company, business entity, or individual (if self-employed) as you would have it appear on the license,
    b. Articles of Incorporation,
    c. Current Business License at the location of use,
    d. Company tax identification number (EIN and State Tax ID number) or Social Security Number (if self-employed),
    e. Physical address (cannot be a P.O. Box),
    f. Mailing address (may be a P.O. Box), and
    g. Company Phone and fax numbers and email address.
2. Billing and Annual Fees
    a. Provide the name, title, mailing address, phone, and email address of the person responsible for accounts payable, and
    b. Provide a check payable to the Radiologic Health Branch for the required annual fees.
3. Change of Ownership
    a. For Change of Ownership amendment requests, please also provide the change of ownership form signed by representatives with financial and legal authority for both, the buyer and the seller, in addition to the items listed above. A sample ownership change form may be obtained online at: https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/RHB/RML/RHB-OwnershipChange.docx
    b. If using Internet Explorer or Microsoft Edge, download the document onto your computer first. Then open the document from your computer.
    c. If you open the document from the website on Internet Explorer or Microsoft Edge, when the Security Dialog box pops up you must click cancel and continue to click cancel until the document content is displayed. The dialog box does not appear on Google Chrome or Firefox.
    d. Provide an Organizational Chart (RSO and above) with names, titles, and phone numbers of individuals.

Appendix B: Radioactive Material Authorization

1. Nuclide
    a. Name the nuclide(s) (e.g., Hydrogen-3, Carbon-14, Iodine-131, etc.)
    b. State maximum activity of each nuclide, and maximum individual source activity for sealed sources (e.g., “Not to exceed 100 millicuries” or “2 sealed sources not to exceed 50 millicuries each”).
    c. Specify the form of the radioactive material (e.g., RIA kits, sealed source, labeled compounds, “Any” form, etc.)
    d. For sealed sources, specify the following:
        i. Manufacturer(s),
        ii. Model number(s) (Sealed source (ABC Corp. Model DEF)),
        iii. Specify the number of sources to be possessed under the license.
2. Proposed Use
    a. Clearly state the intended use of each radionuclide (e.g., “To be used for labeling and as tracers in chemical and biological (in vitro/in vivo) studies”). Note: this type of license does not permit manufacturing and distribution.
3. Changes in Possession Limit
    a. To change Possession Limit, provide a letter requesting the change.
    b. To add a new radionuclide, provide the same information as in sections 1 and 2 of this Appendix, as appropriate.
    c. For a decrease in possession limit for sealed sources, provide the following:
        i. Receipt(s) for transfer of sources signed by both the licensee and the party accepting the sources,
        ii. Radioactive Material License Number of the recipient if a California licensee, or a copy of the Radioactive Material License if an NRC or another agreement state licensee,
        iii. Leak tests of all sources transferred, and
        iv. Disposition documents (e.g., use logs, disposal records, etc.).

Appendix C: Radiation Safety Officer and Authorized Users

1. Radiation Safety Officer (RSO) and Alternate Radiation Safety Officer (ARSO)
    a. Provide a letter from the person with legal and financial responsibility for the company, naming the RSO and ARSO. An ARSO is recommended, but not required.
    b. Provide the phone, fax, cell-phone (24-hr contact phone), and email address for the RSO and ARSO.
    c. Provide the completed Statement of Training and Experience (form RH2050A) for the RSO and ARSO. Experience should be commensurate with the size and scope of the proposed program. Form RH2050A may be obtained online from the Department's website at: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/rh2050a.pdf
    d. Provide copies of any appropriate training certificates.
    e. For the RSO – provide the following:
        i. Duties and Responsibilities form which may be obtained online from the Department's website at: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8243IR4.pdf
        ii. Delegation of Authority form which may be obtained online from the Department's website at: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8243IR1.pdf
    f. For the ARSO – provide the following:
        i. Duties and Responsibilities form which may be obtained online from the Department's website at: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8243IA4.pdf
        ii. Delegation of Authority form which may be obtained online from the Department's website at: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8243IA1.pdf
    g. Provide an Organizational Chart (RSO and above) with names, titles, and phone numbers of individuals.
    h. An updated Emergency Contact List that includes the names and phone numbers (day and 24-hour numbers) of:
        i. RSO,
        ii. ARSO (if applicable),
        iii. Sealed source manufacturer(s) (if applicable),
        iv. Numbers listed for local inspection agency and RHB:
        v. 24 Hour Radiation Emergency Assistance 1-800-852-7550
        vi. RHB Sacramento 1-916-327-5106
        vii. RHB Richmond 1-510-620-3416
        viii. RHB Brea 1-714-524-1409
        ix. RHB Los Angeles County 1-213-351-7897
        x. RHB San Diego County 1-858-694-3621

2. Authorized Users
    a. Submit changes in Authorized Users to the Department. Include the following:
        i. A dated cover letter specifying the changes, signed by the RSO, ARSO, or management,
        ii. Any appropriate training certificates, and
        iii. A completed Statement of Training and Experience (form RH2050A), which may be downloaded from the link provided in section 1(c) of this Appendix.

Appendix D: Radiation Detection and Personnel Monitoring

1. Radiation Detection Instruments
    a. Confirm having an adequate number of survey meters and instruments commensurate with the size and scope of your program. Specify the quantity, manufacturer, and model number of the survey meter(s), probe(s), liquid scintillation counter(s) (LSC), and/or gamma counter(s). The suggested instrumentation for radionuclides typically used in laboratories is as follows:
        i. For beta emitters such as P-32 and S-35, a survey meter with a pancake probe (or a built-in detector) with a window thickness not exceeding 2 mg/cm^2 is recommended for direct surveys.
        ii. For low-energy gamma emitters such as I-125, direct surveys may be made with a survey meter with a thin sodium iodide detector (scintillation probe).
        iii. For licensees using H-3, area smear samples (wipes) counted in a liquid scintillation counter (LSC) are appropriate. Direct survey meters should not be used for this radioisotope.
        iv. All beta and low-energy gamma can be counted by LSC techniques. Note that many gamma and x-ray emitters can be counted more efficiently by a gamma well counter.
        v. For survey meter calibration by an outside service provider, provide the name and radioactive material license number of the authorized service company that will be performing the calibration. To avoid having to submit amendment requests when you wish to change service providers, you may confirm using only authorized service companies. If the provider is not in California, provide their name, address, and telephone number. Specify the frequency of calibration. For information on performing in-house calibration of survey meters, see Appendix J.
        vi. Confirm use of NIST-traceable sources and to follow the manufacturer's calibration procedures when calibrating LSCs and gamma counters. Indicate if these are exempt or non-exempt sources. If non-exempt, they will need to be listed on the license, therefore please provide source information – radionuclide, activity of each source, manufacturer and model number.
2. Personnel Monitoring and Bioassays
    a. Specify the type of dosimeter used (whole body or extremity; Thermoluminescent Dosimeters (TLD), Optically Stimulated Luminescent (OSL) dosimeters, or film), the frequency of exchange, and confirm the use of a NVLAP-approved vendor.
    b. Only individuals handling 1 millicurie or more of high-energy (> 200 keV) beta or gamma emitters would need to be considered for extremity dosimeters.
    c. Describe the bioassay program used when using unsealed volatile radioactive material (see Appendix K).

Appendix E: Facilities and Equipment

1. Adding a use and/or storage location
    a. Provide the address of your facility.
    b. Provide a facility diagram (of buildings and individual rooms) showing the radioactive material use areas, storage areas (specify whether sealed or unsealed material is used in these areas), package receipt area, adjacent areas, animal housing areas, and the location(s) waste disposal sink(s), if applicable. Outline the restricted and unrestricted areas on the diagram per 10 CFR 20.1301. For each room where radioactive material will be used, stored, and/or received, provide an 8 ½" x 11" room diagram showing dimensions.
    c. Specify any shielding used (type and thickness, e.g., acrylic, lead, etc.).
    d. Indicate location of fume hoods and/or glove boxes, if applicable. If using volatile forms of radioactive material, refer to Appendix L for fume hood information and Appendix K for bioassay information.
    e. Describe any other safety equipment used in handling radioisotopes (e.g., safety glasses, tongs, etc.)
2. Decommissioning a Storage/Use Location or Terminating a Radioactive Materials License
    a. For decommissioning a location, or terminating the radioactive materials license, use the following guidelines:
        i. For sealed sources, please follow Guidance for Termination or Decommissioning for Licensees Using Radioactive Material in Sealed Sources.
        ii. For unsealed radioactive material of short half-life (≤ 120 days), please follow Guidance for Termination or Decommissioning for Licensees Using Short Half-life (≤ 120 days) Radioactive Material.
        iii. For unsealed radioactive material of long half-life (≥ 120 days), please follow Guidance for Termination or Decommissioning for Licensees Using Long Half-Life (≥ 120 days) Radioactive Material.

Appendix F: Radiation Safety Program

1. Radiation Safety Program
    a. Submit your Radiation Safety Program (RSP). Include the following in your RSP:
        i. Operating and Emergency Procedures:
            1. Confirm following the General Safety Rules in Appendix G, and to provide a copy of the rules to all users of radioactive material. Alternatively, you may follow your own set of equivalent rules.
            2. Submit your decontamination procedures for spills, accidents, and decommissioning with appropriate action levels for both exposure rate and wipe results. See section 4 of this Appendix.
            3. Submit your Operating and Emergency Procedures. Confirm keeping them up-to-date. Include the Emergency Contact List from section 1h of Appendix C, and conspicuously post the Emergency Contact List.
    b. Confirm providing initial radiation safety and annual refresher training for occupational workers and ancillary staff. The training should include operating and emergency procedures, and relevant state and federal regulations. For new and renewal applications, provide an outline of the training, the duration of training, and the method of documentation (e.g., a signed attendance sheet). Confirm that the topic of pregnancy declaration will be addressed (refer to NRC Regulatory Guide 8.13).
    c. Submit shipping, receiving, opening, ordering and inventory control procedures along with sample forms. Package receipt surveys should be done using an ion chamber or energy-compensated probe able to read the radiation levels found in Appendix N, item 5 (see Appendix N for package receipt procedures).
    d. Confirm performing an annual audit of the program. Confirm keeping records available for inspection (see 10 CFR 20.1101 and 10 CFR 20.2102).
    e. Confirm conspicuously posting form RH-2364 (Notice to Employees), the license, operating and emergency procedures, and state and federal regulations. If not practical, post a notice stating where all items may be found. Confirm posting radioactive material signage per 10 CFR 20.1902 and 17 CCR Section 30255.
    f. Confirm that all containers, storage areas, rooms, and equipment in which radioactive materials are used are properly labeled in accordance with 10 CFR 20.1904.
    g. Provide routine survey procedures appropriate to the types and quantities of radioactive material proposed in the application. Good laboratory practices recommend surveying work areas at the end of the day. Confirm performing routine surveys and keeping records of the surveys for inspection. Be sure to indicate on the diagram(s) where readings will be taken.

i. Surveys should include both direct survey meter readings and area wipes as applicable. Provide action levels for decontamination. Specify how background readings will be determined. Please be sure to record the background reading as a reference. Note: If you are using H-3, perform wipe surveys or provide wipe survey results. See Appendix D, section 1c. Confirm having a number of survey locations commensurate with the size and scope of the program. Partial room surveys are not acceptable.

h. Confirm maintaining all records required per 10 CFR 20.2101 through 20.2110. For a list of the types of records to be maintained, see Appendix P.

2. Effluent and Environmental Monitoring
   a. If performing sanitary sewer releases, confirm meeting the criteria stated in 10 CFR 20.2003.
   b. If performing iodinations, refer to Appendices L and O for information on stack effluent releases.
3. Waste Disposal
   a. For sanitary sewer releases, refer to section 2(a) of this Appendix.
   b. For waste packaging, describe disposal of liquid scintillation vials, solid and liquid waste, and animal carcasses, if applicable. If transporting waste, confirm quality assurance on waste drums (wipe tests, exposure reading, and tilt test). Confirm the waste storage area is covered and secured. Radioactive waste must be disposed of in accordance with regulatory requirements (10 CFR 20.2001) and appropriate records of waste disposal must be maintained, including the current authorized broker.
   c. For the decay-in-storage method of waste disposal, confirm following Appendix I.
4. Decommissioning and Decontamination Plans
   a. To decommission a use location:
      i. Confirm that you will prove the Department with a 30-day written notification of your intent to vacate a use location.
      ii. Provide a decommissioning survey with proposed release criteria.
      iii. Confirm that the location(s) will not be released for unrestricted use until an amendment releasing the location is issued by the Department.
   b. For licenses with large quantities of radioactive material, a Decommissioning Funding Plan (DFP) and/or financial surety will be required. Refer to 10 CFR 30.35 and NUREG-1727 Volume 3 for more information.

Appendix G: General Safety Rules

1. Use protective clothing and impermeable gloves.
2. Use trays which will hold the contents in the event of spills or breakage of containers during storage or transport between laboratory areas and in common hallways.
3. Line trays and working surfaces with absorbent backed paper.
4. Store liquid forms of radioactive materials in sealed containers.
5. Use syringe shields.
6. Properly label all containers and storage and use areas in accordance with 10 CFR 20, Subpart J.
7. Keep a log of all radioactive materials.
8. Store high energy beta and all gamma emitters in properly shielded containers.
9. Use remote handling tools when appropriate to minimize extremity exposures.
10. Use appropriate dosimeters to monitor exposure to radiation.
11. Transport and work with radioactive materials in accordance with radiation safety operating and emergency procedures.
12. Monitor work areas, hands, and clothing whenever there is a possibility of contamination and after each day of use.
13. Clean up spills promptly in accordance with written instructions.
14. Prohibit eating, drinking, smoking, or applying cosmetics in areas where unsealed radioactive materials are used.
15. Prohibit pipetting by mouth (use remote pipettes only).

Appendix H: Survey Frequencies for Laboratories

To assure consistency in requirements for routine surveys at laboratories, follow the general guidelines specified below. For more information, see NUREG-1556, Volume 7, Revision 1, Appendix M.

For any individual laboratory use area (room), in addition to any daily surveys for personnel contamination or suspected surface contamination, direct meter surveys (if applicable) and area smear surveys shall be performed at the following intervals:

Quantities in Use	Survey Frequency
< 0.1 ALI	Monthly (or after each use if used less than monthly)
≥ 0.1 ALI < 1.0 ALI	Weekly (or after each use if used less than weekly)
≥ 1.0 ALI	Daily (or after each use)
Not in Use	6 months

If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

Note: Records of such surveys are required to be maintained for inspection. Daily (or after each use) checks for personnel contamination and suspected facility contamination by individual users need not be recorded, unless a positive result is detected. In these cases, proper actions relative to notification, decontamination and corrective measures shall be taken.

Appendix I: Checklist for the Decay-in-Storage Method of Waste Disposal

1. Confirm that only radionuclides (sealed and unsealed) with half-lives less than or equal to 120 days will be considered for DIS.
2. Submit a description and a diagram of the area where the waste will be held in storage. Describe the shielding and security. Confirm that postings will meet the requirements of 10 CFR 20.1902.
3. Provide the frequency of surveys of adjacent areas and the DIS area along with the survey map and form in which survey results will be recorded.
4. Confirm that dose rates in adjacent unrestricted areas will not exceed 0.05 mrem/hr above background radiation levels or propose and justify higher limits that comply with 10 CFR 20.1301 and 10 CFR 20.1302.
5. Provide survey procedures including the following:
    a. Confirm that the inventory control system used to track individual bags, boxes, or other containers will include isotopes, activities, and date sealed and placed in storage.
    b. Confirm that waste will be held for a minimum of ten (10) half-lives prior to release from DIS.
    c. Confirm that waste will be surveyed and determined to be indistinguishable from background prior to disposal. The surveys are to be performed in low background areas that are not impacted by licensed radioactive materials.
    d. Identify instrumentation (see table below) used to perform surveys in the low background area. Surveys should include all outer surfaces of each container to be released (i.e., scan within 1 inch of the surface at a scan rate not greater than 1 inch per second).

Type of Radiation	Recommended Instrument
Pure Beta (P-32, S-35, Y-90)	GM pancake or equivalent (<2.0 mg/cm^2 window)
Low Energy Gamma or X-ray (I-125, Pd-103)	Thin crystal NaI (1” x 1 mm)
Moderate Energy Gamma or X-ray (Tc-99m, Ga-67, Tl-201, Cr-51, Co-57, In-111, I-123, Ra-223)	Thin crystal NaI (1” x 1 mm) or Thick crystal NaI (1” x 1”)
High Energy Gamma or X-ray (I-131, PET isotopes)	Thick crystal NaI (1” x 1”)

    e. Confirm that waste will be segregated by half-life groups and type of emitted radiation.
6. Recommended instruments are listed in Table 1. If different instrumentation is proposed, submit supporting information, including the manufacturer’s technical specifications of the instrument/system, to demonstrate that the instrumentation is appropriate for distinguishing above background radiation levels for the isotopes of concern.
7. Confirm that if new isotopes are added to the DIS program, instruments used for release surveys will be based on Table 1 or submit the new instrument to RHB for approval.

8. Confirm that all labels or similar markings, which indicate the presence of radioactive materials, will be removed or obliterated. This can be done as the waste is placed in containers, leaving only the outer container labels to be removed prior to release. If the waste is destined to be disposed of at a biomedical waste facility, internal labels do not need to be removed.
9. Confirm that the waste/DIS log will include disposal date, type of waste, surveys results, serial number for sealed sources, instrumentation used, and the name of the surveyor and will be maintained for (3) three years or until the next inspection.

Appendix J: Instrument Calibration Procedures Checklist

This checklist identifies items which need to be included to obtain authorization for calibration of instruments for in-house use or as a customer service. Additional information may be found in ANSI N323-1997 and NUREG-1556, Volume 7, Appendix M.

1. Exposure Rate Meters:
    a. A facility diagram showing the location of the calibration device and range. Include expected or measured radiation levels in adjacent uncontrolled areas.
    b. Describe security and posting of the area when the unit is in use.
    c. Provide the manufacturer and model number of the calibration device and sealed source(s) contained within the device, as well as the isotope and activity of the source(s).
    d. Confirm following ANSI N323A-1997 or provide the following information:
        i. Assure NIST traceability to within 5 percent of the true activity of the calibration source or output (using thimble ion chambers). A 100 mCi source is considered adequate for calibration of ranges up to 1 R/hr. Smaller sources may be used for calibrating limited ranges (specify, if applicable).
        ii. Provide step-by-step operating procedures which include radiation safety precautions and personnel dosimetry. A minimum of 2 points per scale, separated by 50 percent full scale shall be included for each scale certified as calibrated to ± 10 percent (or to ± 20 percent with chart or graph attached to the instrument).
        iii. Attach a sample reporting form given to the customer or used to keep records for inspection.
        iv. Confirm performing an annual recharacterization of your working standard.
2. Contamination Survey Meters:
    a. Contamination survey meters with a known cpm or mR/hr conversion may be calibrated as above, or:
        i. Provide procedures which include the use of a pulse generator and a NIST-traceable source of sufficient strength to determine the efficiency of the probe.
        ii. Submit sealed source handling precautions and dosimetry as needed.
        iii. Refer to Items 4(b) and 4(c) above regarding calibration points, certification, and reporting forms.
    b. If the user requires gamma and/or beta efficiency, address the following:
        i. Confirm obtaining NIST traceable sources of similar radiations and energies to the types the end user would encounter.
        ii. Submit the MDA equations that you will use, along with references. Alternatively, confirm that you will use the following Minimal Detectable Activity equation (or derivations) based on NUREG 1400:
            1. For scalers:

$$\text{MDA (dpm / 100 cm}^2) = 4.65\sqrt{\frac{R_b}{E(\frac{A}{100})}}$$

2. For rate meters:

$$\text{MDA (dpm / 100 cm}^2) = 4.65\sqrt{\frac{R_b/2T}{E(\frac{A}{100})}}$$

iii. Refer to Items 4(b) and 4(c) above regarding calibration points, certification, and reporting forms.

3. Pocket Dosimeters:
   a. Refer to ANSI N13.5-1972 (available from the Department).

Appendix K: Requirements for a Bioassay Program

This checklist serves to identify information to be submitted for authorization to either be a service provider or perform bioassay for your own employees.

1. Thyroid Bioassay Program:
    a. Submit the following:
        i. Specify isotopes to be considered (e.g. I-125, I-123, and/or I-131).
        ii. Submit a description and diagram of the measurement system, including the instruments, neck phantom, and the room it will be performed in.
        iii. Provide the manufacturer and model number of the instruments used to do the counting.
        iv. Describe the neck phantom (ANSI standard N44.3-1973) and the NIST traceable standard (rod) source (exempt) used for calibration (Regulatory Guide 8.20).
        v. Provide the procedures used to calibrate the system, specify the frequency of calibrating the system, and demonstrate an adequate minimum detectable activity (MDA) for the system (15 nanocuries or less).
        vi. Provide the procedures for making the actual measurements and conversion of CPM to micro curies in the thyroid.
        vii. Describe how the microcurie results are converted to dose and ensure that the CEDE is determined for employees.
        viii. Confirm the action levels or investigational level using the thyroid burden results (no more than 10% of ALI) and how the results will be recorded and maintained for each employee.
        ix. Confirm performing a baseline measurement for new workers prior to working with the material and if the employee is leaving the position, perform a final measurement and dose summation.
        x. Specify routine frequency of monitoring and performing a special bioassay on an as-needed basis in case of a possible uptake during a spill or accident.
    b. If radioiodine is detected in the thyroids of personnel, it is recommended that air samples in the room should be checked to determine if there is a problem with ventilation in the laboratory. Action levels for I-125 can be set for 10 % of the Derived Air Concentration (DAC) in air (approximately 3 x 10^{-8} microcuries/ml of air). If the action level counted in the charcoal filter exceeds this amount, the ventilation system should be checked and iodination procedures reviewed.
2. Bioassays for H-3, C-14, P-32, or other isotopes:
    a. Please provide the information listed above, as applicable to the isotope being measured, such as the equipment, procedures, method of counting, action or investigational levels, MDA, frequency of monitoring, and method of converting the result to a dose.
3. Personnel Monitoring Requirements for Internal Exposure
    a. The licensee shall monitor occupational intakes of radioactive material by, and assess the committed effective dose equivalent to, individuals who

may have exceeded or are likely to exceed, the limits specified in 10 CFR 20.1502(b). Suitable and timely measurements used for determination of such internal exposures shall be performed as specified by Section 20.1204.

4. References
    a. Reg. Guide 8.9 “Acceptable Concepts, Model, Equations and Assumptions for a Bioassay Program”.
    b. Reg. Guide 8.20 “Application of Bioassay for I-125 and I-131.”
    c. NUREG – 1556, Volume 7, Appendix Q.
    d. ANSI HPS N13.14-1994, “Internal Dosimetry Programs for Tritium Exposure - Minimum Requirements”.
    e. US NRC, Code of Federal Regulations, 10 CFR 20.1204.
    f. NUREG/CR 4884/BNL-NUREG-52063 “Interpretation of Bioassay Measurements”, Appendix B (Page B-711)is a table for retention and excretion for H-3, (page B-484) for P-32, (Page B-587) for I-131.
    g. ICRP 30, Part 1, Limits for Intakes of Radionuclides by Workers, “Metabolic Data for Phosphorous”.

Appendix L: Checklist for Effluent and Environmental Monitoring for Stack Releases

1. Effluent Monitoring
    a. Submit ventilation drawings for your facility including fume hoods, intakes, exhausts, and filtration. On the ventilation drawing, provide various measurements including the duct diameter, cross sectional areas, and duct lengths.
    b. Specify the exhaust flow rate for your facility and the frequency at which you will determine exhaust flow rates. Describe how the flow rates are determined and the error associated with the measurements.
    c. Provide details of your effluent monitoring program including: sample plans, instrumentation, set points, operating procedures and assumptions, or provide calculations and justifications as to why an effluent program is not needed.
    d. Submit an alarm set point (based on ALARA requirements in 10 CFR 20.1101(d)) that is set below the applicable limit found in 10 CFR 20 Appendix B. You may also submit your own limit as long as it is justified and you submit all calculations, assumptions, and data for review.
    e. Provide actions the licensee will take once an alarm actuates.
    f. Confirm ceasing operations if your effluent monitoring system is unable to function.
    g. Submit a calibration procedure to test your inline effluent monitoring system with the effluent or its equivalent (RHB suggests a minimum of three times using N-13 or F-18 not in FDG form) to determine a calibration factor for your system along with a total error. Individual calibration factors should all be within an order of magnitude of each other.
    h. Describe the record-keeping format of your system.
2. Physical Measurement Submission
    a. Submit physical measurements (vault exposure rate survey) to confirm the integrity of the shielding.
    b. Submit effluent test results.
    c. Confirm all interlocks were tested and are operating within design specifications.
    d. Submit Minimal Detectable Concentration calculations along with all assumptions justified (counting time, etc.).
    e. Propose and justify effluent release limits for those isotopes not found in 10 CFR 10 Appendix B.
    f. Describe your annual calibration procedures.
    g. Alarm monitor test results.

Appendix M: Checklist for In-vivo Procedures with Small Animals

Provide the following:

1. A description of the animal housing facilities (room number/name, room diagram, and postings).
2. A copy of the radiation safety instructions provided to animal care takers for handling animals, animal wastes and carcasses.
3. Confirm that all waste disposal records will be maintained.
4. Written instructions for cleaning and decontaminating cages including the criteria for decontaminating and what is considered acceptable.
5. Procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized personnel.

Note that animal waste and cleaning water/material is not exempt from being considered as radioactive waste unless it meets the requirements found in 10 CFR 20.2005 – Disposal of Specific Wastes. If you wish to use sink disposal, please refer to the information needed in Appendix F section 3.

Appendix N: Package Receiving and Opening Procedures

The licensee shall perform the monitoring required by 10 CFR 20.1906 as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Received packages will be monitored for removable surface contamination and external radiation levels as follows; only by persons specifically trained in package opening procedures:

1. Check for signs of damage to the package. If there is any sign of damage, measure the radiation level at the surface and measure the external surface removable contamination. If the radiation level is greater than twice background reading, or the external surface contamination is greater than 200 dpm/100 cm^2, decontaminate and record the reading, as part of the ALARA procedures.
2. If no sign of damage, measure the surface removable contamination. If the contamination level is greater than 200 dpm/100 cm^2, decontaminate and record the reading, as part of the ALARA procedures.
3. In either case, step 1 or 2, monitor the final source container for removable contamination. If the contamination level is greater than 200 dpm/100 cm^2, decontaminate and record the reading, as part of the ALARA procedures. You should notify the vendor as well.
4. Make entry in the inventory log and store the radioactive material in a designated storage area.
5. Per 10 CFR 20.1906(d), you must immediately notify the final carrier and the regulatory agent if:
    a. Removable external surface contamination exceeds the limits given in 10 CFR 71.87(i), or
    b. Radiation levels at any point on the external surface exceed the limits given in 10 CFR 71.47.

Appendix O: Checklist for Radioiodinations

1. Specify the isotope (I-125, I-131) and chemical form.
2. Indicate which room at the facility the procedures will be performed.
3. Specify the approximate amount of activity used per iodination.
4. Confirm the use of shielding around the source container, and the use of remote handling tools (e.g., tongs), when appropriate.
5. Confirm the radioiodination procedure will be performed as applicable in a fume hood.
6. Confirm the source container will be kept in a fume hood.
7. Confirm that gloves will be worn prior to handling and use.
8. Confirm the fume hood will have a minimum of 100 linear feet per minute exhaust. A magnehelic gauge may be used to measure the pressure drop when the filter has built up particles.
9. Please indicate the survey frequency and action level for the room if different from other radioactive use locations.
10. Confirm by various methods that radionuclides exhausted will not exceed the stack effluent release limits in 10 CFR Part 20 Subpart D by either of the following:
    a. Demonstrate by calculation using the amounts they anticipate using that they won't exceed the limits.
    b. Using a 2 filter system (charcoal filters) in the fume hood exhaust, procedures on surveying and filter exchange procedures, frequency.
11. Confirm the iodination fume hood has an independent exhaust stack.

Appendix P: Records to be Maintained

This is a list of records that should be maintained at a minimum. Please refer to 10 CFR 20 Subpart L and Title 17 CCR 30256 and 30293 for regulatory requirements.

1. Receipt and Package Surveys
2. Inventory
3. Area Surveys
4. Disposal (sanitary sewer, drummed waste, store for decay)
5. Instrument Calibrations
6. Dosimetry/Bioassays
7. Training Sessions/Attendees