

LICENSING GUIDELINES FOR MEDIUM (10 – 100 mCi) AND LARGE (>100 mCi) LABORATORIES

For New, Renewal or Amendment Applications

This is a general guideline to assist those applicants wishing to obtain licensure for laboratories. All forms and checklists are available at the [RHB Website](http://www.cdph.ca.gov/rhb) (www.cdph.ca.gov/rhb). Provide the following information and/or descriptions noted below on form RH-2050 or attachments thereto. Please use the appropriate Appendices (A-L) as applicable to the proposed program. The Appendices are used as guidelines and you may propose equivalent information applicable to your individual program. All correspondence must be submitted in duplicate. *To facilitate the review, please submit the information in the order as itemized below.* The license amendments, applications and renewals will be reviewed in the order received.

Please note, that licensing fees must be included with new applications and amendments that require an increase in fees. Fees must be current for amendments and renewals (see our website for fee information the [RHB Website](http://www.cdph.ca.gov/rhb) (www.cdph.ca.gov/rhb)).

Item 1.

- a. **Name of Applicant:** Specify the name of the company or business entity responsible for the radiation safety program. If there is a parent company, please specify and indicate the name you prefer on the license.
- b. **Mailing Address:** Include contact person's name.
- c. **Billing Address:** Include contact person's name.
- d. **E-mail Address:** If available.
- e. **California Phone** and Fax Number.

Item 2.

- a. **Type of Business:** If government, indicate here.
- b. **Location of Use:** List addresses of all locations of use/storage, include room designation, numbers and if a multi-story building, specify which floor this location is on (see Item 9 for additional requirements). *P.O. Box is not acceptable.*
- c. **Application Type:** Self explanatory.
- d. **Provide California Tax ID Number.**

Item 3.

- a. **Nuclide(s):** Specify all isotopes/nuclides to be used; (e.g. Hydrogen-3, Phosphorous-32).
- b. **Form:** Specify the chemical/physical form for each isotope; (e.g. RIA kits, labeled compounds, "Any" form, sealed source). Submit the manufacturer and model number for each sealed source.
- c. **Possession Limit:** State the *maximum* inventory (specified in units of microcuries, millicuries and/or curies) to be in possession at any one time (including radioactive waste in storage) for each isotope. Specify the maximum activity for each sealed source and the total possession limit. If you plan to have very large quantities of radioactive material, such as curie amounts, please reference information on our website on Increase Controls. There may be additional requirements for control over the radioactive material.

Item 4. Proposed Use:

Summarize the proposed use and include typical amounts used per experiment for each isotope (e.g. in-vitro, in-vivo studies, RIA kits, tracer studies). For In-vivo studies, see **Appendix G**, and for iodination procedures, see **Appendix K**.

Please indicate if you wish to manufacture/distribute Radio-Immune Assay (RIA) in-vitro test kits to *general* licensees. A specific distribution license is required to do so. You may download this checklist the [RHB Website](http://www.cdph.ca.gov/rhb) at (www.cdph.ca.gov/rhb) and submit a separate RIA Kit Distribution application for a license.

Item 5. Radiation Safety Officer (RSO), Alternate Radiation Safety Officer (ARSO) and Authorized Users:

Provide completed Training and Experience form (RH-2050A) for the RSO, ARSO and supervisory authorized users (Title 17, Section 30194). Submit a completed Duties and Responsibilities and Delegation of Authority form (see **Appendix B**).

Submit an organizational chart relative to the radiation program. Please be sure to include names and titles of individuals above the RSO's position.

Note: It is recommended that an ARSO be listed on the license to provide program oversight in the absence of the RSO.

Item 6. Radiation Detection Instruments:

Complete the table indicated under Item 6 of the application. Commit to having an adequate number of survey meters and instruments commensurate with the size and scope of the program. Specify the quantity, manufacturer and model number of the survey meter(s), probe(s), liquid scintillation counter (LSC)

and/or gamma counter. The suggested instrumentation for nuclides typically used in laboratories is as follows:

Survey meters and probes

- a. For beta emitters such as P-32 and S-35, a survey meter with a pancake probe (or built in) with a window thickness not exceeding 2 mg/cm² is recommended for direct surveys. For C-14, a survey meter with a thin end-window probe may be used for surveys.
- b. 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).

Liquid Scintillation and Gamma Counters

- a. For H-3 use *only*, area smear survey samples (wipes) can be counted in a liquid scintillation counter (LSC). Direct meter surveys should not be used for this isotope.
- b. All beta and low energy gamma emitters can be counted by LSC techniques. Note that many gamma or X-ray emitters can be counted more efficiently by a gamma well counter.

Item 7. Method, Frequency, and Standards Used in Calibrating Instruments Listed Above:

- a. Outside Service Company: Provide the name and radioactive material license number of the authorized service company who will be calibrating the survey meters. You may commit to utilizing any other authorized service company to avoid amendments involving such a change in the future. If the provider is not in California, provide their name, address and phone number. Specify the frequency of calibration. See **Appendix D** for information on in-house calibration of survey meters.
- b. Commit to using NIST traceable sources and to follow the manufacturer's calibration procedures when calibrating LSC and gamma counter. Indicate if these are received as exempt sources or should be listed as non-exempt radioactive material on the license (isotope, activity of each, manufacturer/model #).

Item 8. Personnel Monitoring and Bioassays:

Only individuals handling 1 millicurie or more of high energy (> 200 keV) beta or gamma emitters would need to be considered for extremity dosimeters. Specify type (whole body, extremity; Thermoluminescent Dosimeters (TLD), Optically Stimulated Luminescent (OSL) Dosimeters or film), approved vendor, and the frequency of exchange. If film badges are used, commit to a monthly

exchange frequency. Also, you may commit to using any National Voluntary Laboratory Accreditation Program (NVLAP) approved organization to change the vendor without notifying us through an amendment.

Describe the bioassay program when using large quantities and/or volatile radioactive material (see **Appendix E**).

Item 9. Facilities and Equipment:

- a. Provide a facility diagram (building and room diagrams) showing the specified floors if it is a multi-story building, the radioactive material use areas, storage areas for unsealed and sealed material, package receipt area, location of fume hood(s), waste disposal sink(s) (if applicable), adjacent areas, and animal housing area (if applicable). Provide an 8 ½" x 11" room diagram with dimensions for each room where radioactive material will be used, stored and/or received. Outline the restricted and unrestricted areas on the diagram per 10 CFR 20.1301.
- b. Specify any shielding to reduce exposures of radiation to workers (type and thickness, e.g. acrylic, lead, foil).
- c. Indicate location of hoods and/or glove boxes: Refer to **Appendix F** for fume hood information and **Appendix E** for Bioassay information, if using volatile forms of radioactive material.
- d. Describe any other safety related equipment (e.g. safety glasses, tongs) used in handling isotopes.
- e. Describe the security over the radioactive material during times of normal use and after hours. Commit to direct surveillance while in use and secured when not in use per 10 CFR 20.1801 and 1802. For after hour deliveries, submit the package receipt procedures and instructions, and confirm appropriate posting and security (see **Appendix J** for package receipt information).

Item 10. Radiation Safety Program:

- a. Operating and Emergency Procedures:
 1. Provide a copy of the "General Safety Rules" which will be followed by all users of radioactive materials (see **Appendix C**). If you wish to conform to the General Safety Rules in **Appendix C**, please commit to using the proposed General Safety Rules.
 2. Submit the decontamination procedures for spills, accidents and decommissioning with appropriate action levels for both exposure rate and wipe results.

3. Submit the emergency and operating procedures. Commit to keep them updated and conspicuously post the emergency call list (24-hour emergency assistance number ((800) 852-7550) and the RHB-Sacramento number ((916) 327-5106). Be sure to include the regular and after hours telephone numbers for the RSO and ARSO.

b. Training:

Commit to providing initial radiation safety training and annual refresher training for occupational workers and ancillary staff (Title 17, Section 30194 (a)(1)). The training should include emergency and operating procedures, and relevant state and federal regulations. For new and renewal applications, provide an outline with the topics, state the duration of training and how the training will be documented (such as a signed attendance sheet). Be sure to cover the topic of pregnancy declaration (refer to NRC Reg. Guide 8.13).

c. Procedures for Shipping, Receiving, Opening and Ordering Packages:

Submit shipping, receiving, opening, ordering and inventory control procedures with sample forms. Package receipt surveys should be done as with an ion chamber or energy compensated probe to read the radiation levels found in Appendix J, item 5, found in the transportation regulations (see **Appendix J** for package receipt procedures).

- d. Submit Shipping Procedures only if authorized for distribution. Commit to following Department of Transportation (DOT) requirements for shipping radioactive material. The DOT hotline number for questions is: (800) 467-4922.
- e. Commit to performing an annual audit of the program. Commit to keeping records available for inspection (10 CFR 20.1101).
- f. Commit to conspicuously post 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. Commit to post radioactive material signage per 10 CFR 20.1902 and Title 17, Section 30255.
- g. Commit that all containers, storage areas, rooms, and equipment in which radioactive materials are used are properly labeled in accordance with 10 CFR 20.1904.
- h. Provide routine survey procedures appropriate to the types and amounts of radionuclides proposed in the application. Good laboratory practices recommend surveying work areas at the end of the day. Commit to performing routine surveys and keeping records of the surveys for inspection. Refer to **Appendix H** for determining routine survey frequencies based on the quantities in use. Be sure to indicate on the diagram(s) where readings were taken.

These surveys are for both direct meter and area wipes. An action level of 200 dpm per 100 cm² removable activity limit and a 0.1 mR/hr or less direct reading limit is recommended 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, only wipe surveys are recommended. Wipes must be analyzed using a LSC. Commit to performing the number of survey locations commensurate with the size and scope of the program. Partial room surveys are not acceptable.

- i. Records: Commit to maintain all records per 10 CFR 20.2101 thru 20.2110. See **Appendix L** for types of records that need to be maintained.

Item 11. Effluent and Environmental Monitoring:

Provide procedures if applicable.

- a. Sanitary sewer releases: Commit to meeting the criteria stated in 10 CFR 20.2003 and provide sample calculations.
- b. Stack effluent: If performing iodinations, please refer to **Appendix K**.
- c. Vegetation/soil sampling:

Item 12. Waste Disposal:

- a. Refer to Item 11a for sanitary sewer releases.
- b. For waste packaging, describe disposal of liquid scintillation vials, solid and liquid waste, animal carcasses, if applicable. Confirm quality assurance on waste drums (wipe tests, exposure reading, tilt test). Confirm the waste storage area is covered and secured. For new and renewal applications, provide the authorized waste broker or waste processor and their radioactive materials license number, if in California. Radioactive material waste must be disposed of in accordance with regulatory requirements (10 CFR 20.2001) and appropriate records of waste disposal must be maintained.
- c. For the decay in storage method of waste disposal, specify the isotopes (physical half-life less than 90 days), specify the number of half-lives to elapse (7 or 10 half-lives), survey prior to disposal, and label removal or defacement. See **Appendix I** for additional information. You may commit to following **Appendix I** or provide equivalent.

Item 13. Decommissioning and Decontamination Plans:

Commit to a thirty-day (30) written notification of your intent to vacate a use location(s). Provide a clearance survey to the Department. Commit that the area(s)

will not be released for unrestricted use until an amendment is issued by RHB for release.

Note: To comply with regulations regarding decommissioning funding plans (DFP) and/or financial surety (for licenses that have large quantities of radioactive material), please refer to 10 CFR 30.35 and NUREG 1727.

Item 14. Certificate:

The application should be signed by an official who has legal and financial authority (i.e. President, Vice President, CEO, COO, owner) for the licensee identified in Item 1 (name of applicant) of the application. Please print and sign name in the designated area on the application.

Note: Any false statement(s) in the application or submittals may lead to the license being modified, suspended or revoked by the Department per Title 17, section 30205 (b)(1).

Appendix A

Licensing Checklist for Small Irradiators

This checklist is intended for those applicants wishing to obtain licensure or renewal for utilization of self-contained irradiators (sealed source remains shield at all times, dry storage). Include the information specified below on form RH 2050 or attachments thereto. General information can be found in the guide, form RH 2051.

Item 1. Name of Applicant:

Specify the name of company, business entity, or individual (if self-employed).

Item 2. Self Explanatory

Item 3. Nuclide, Form, Possession Limit:

- a. Cesium 137, Cobalt 60, etc.
- b. Sealed sources (XYZ Co., Model 123
- c. Number of sources (or arrays) and activity each (in curies)

Item 4. Proposed Use:

To be used as a component of a JKL, Inc., Model 456 irradiator for sterilization of blood products (specify intended use).

Item 5. Radiation Safety Officer (RSO) and Users:

Provide a completed form RH 2050A for the RSO and supervisory-users only. If no previous training, specify the training which will be received upon installation by the manufacturer's representative under Item 3, c.

Items 6, 7, & 8.

Not usually required; consult with the manufacturer.

Item 9.

Provide a diagram showing the proposed (or actual) location of the device. Show adjacent uncontrolled areas and specify security provisions to prevent unauthorized use. Consider dose rates in occupied areas near the device.

Item 10. Radiation Safety Program:

- a. Posting RH 2364 (Notice to Employees) and information where the license and regulations can be found.
- b. Submit operating and emergency procedures (available from the manufacturer).
- c. Leak test procedures:
 - Specify the frequency (six months)
 - Specify the wipe test kit used to collect the sample.
 - Specify how the sample will be collected and who will perform the analysis.

Item 11.

Not Applicable

Item 12. Waste Disposal:

Commit to returning the device to the manufacturer or transfer to another specific licensee.

Item 13. Decommissioning and Decontamination Plans:

Commit to thirty (30) day prior notification of your intent to vacate the facility or to relocate the device.

Item 14. Certificate:

Signature and title of management individual who can commit policy for the applicant listed in Item 1 above.

Note: See our website on Increase Controls regarding additional security requirements.

Appendix B

Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority for Research and Development Laboratory Facilities

RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with California and Federal NRC regulations and the conditions of the license. These duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures to personnel are ALARA
- Follows all applicable parts of 10 CFR Part 20 and dose investigational levels
- Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions
- Individuals installing, relocating, maintaining, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed radioactive material (initial and refresher training)
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained. The results given the employee at least annually.
- Licensed material is properly secured

Appendix B (continuation)

- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, or fire (emergency phone numbers are kept current)
- Audits of the radiation protection program are performed at least annually and documented
- If violations of regulations, license conditions or program weaknesses are identified, effective corrective actions are developed, implemented, and documented
- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained, amendment and renewal requests are submitted in a timely manner
- Provide periodic on-site direct supervision over the implementation of the Radiation Safety Program in technical and administrative issues
- Dose records and surveys are reviewed quarterly to ensure safe operations, adequate staff training and engineering controls and to look for trends
- ALARA practices are being followed
- Ensure new users and uses of radioactive material are reviewed prior to first use

Note: In the event of a proposed change in the facility's RSO or license termination, you are aware of and agree to remain the licensee's RSO *until RHB amends this license to reflect this request.*

Appendix B (continuation)

Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the California Department of Health Services, Radiologic Health Branch at anytime. You will directly manage the radiation safety program and be physically present at this facility (and any other use locations listed in the Radioactive Materials License) whatever time as may be necessary to ensure that the radiation protection activities are performed.

_____/_____/_____
Signature of Management Representative * / Print or Type Name / Title

I accept the above responsibilities,

_____/_____/_____
Signature of Radiation Safety Officer / Print or Type Name Date: _____

cc: Affected department heads

* Examples of Management representatives with signature authority are:
Owner, Chief Executive Officer, Chief Operating Officer, President or Vice
President of the organization.

Appendix C

General Safety Rules

1. Use of protective clothing and impermeable gloves.
2. Use of 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. Lining of trays and working surfaces with absorbent backed paper.
4. Storage of liquid forms of radioactive materials in sealed containers.
5. Properly labeling all containers, storage and use areas in accordance with 10 CFR 20, Subpart J.
6. Storage of high energy beta and all gamma emitters in properly shielded containers.
7. Use of remote handling tools when appropriate to minimize extremity exposures.
8. Use of appropriate dosimeters to monitor exposure to radiation.
9. Working with radioactive materials in accordance with radiation safety operating and emergency procedures.
10. Monitoring work areas, hands and clothing whenever there is a possibility of contamination and after each day of use.
11. Cleaning up spills promptly in accordance with written instructions.
12. Prohibition of eating, drinking, smoking or applying cosmetics in areas where unsealed radioactive materials are used.
13. Prohibition of pipetting by mouth (remote pipettes only).

Appendix D

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 N323-1978.

Exposure Rate Meters:

1. A facility diagram showing the location of the calibration device and range. Include expected or measured radiation levels in adjacent uncontrolled areas.
2. Describe security and posting of the area when the unit is in use.
3. Provide the manufacturer and model number of the calibration device and sealed source(s) contained within the device (isotope and activity of the source(s)).
4. Assure NIST traceability to within 5 percent of the true activity of the calibration source or output (using thimble ion chambers). Submit a copy of the calibration certificate for the calibration source. 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).
5. Provide step-by-step calibration 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 with ± 10 percent (or to ± 20 percent with chart or graph attached to the instrument).
6. Attach a sample reporting form given to the customer or used to keep records for inspection.

Contamination Survey Meters:

Contamination survey meters with a known cpm or mR/hr conversion may be calibrated as above, or:

1. 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.
2. Submit sealed source handling precautions and dosimetry as needed.
3. Refer to Items 5 and 6 above regarding calibration points, certification, and reporting forms.

Appendix D (continuation)

4. If the user requires beta efficiency (C-14, S-35, or P-32), describe the beta standards to be used and how fixed geometry is maintained.

Pocket Dosimeters:

Refer to ANSI N13.5-1972.

Appendix E

Requirements for a Bioassay Program

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

Thyroid Bioassay Program,

Submit the following:

1. Specify isotopes to be considered (e.g. I-125, I-123, I-131).
2. Submit a description and diagram of the measurement system, including the instruments, neck phantom, and the room it will be performed in.
3. Provide the manufacturer and model number of the instruments used to do the counting.
4. Describe the neck phantom (ANSI standard N44.3-1973) and the NIST traceable standard (rod) source (exempt) used for calibration.
5. 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).
6. Provide the procedures for making the actual measurements and conversion of CPM to micro curies in the thyroid.
7. Describe how the micro curie results is converted to dose and ensure that the CEDE is determined for employees.
8. Describe the action levels or investigational level using the thyroid burden results and how the results will be recorded and maintained for each employee.
9. Commit to 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.
10. Specify routine frequency of monitoring and performing a special bioassay on an as needed basis incase of a possible uptake during a spill/ accident.

Appendix E (continued)

If personnel are showing radioactive iodine levels in their thyroid after using iodine (over 0.12 microcuries), it is recommended that air samples in the room should be checked to determine if there is a ventilation problem in the laboratory. Action levels for I-125 can be set for 10 % of the Derived Air Concentration (DAC) in air (around 3×10^{-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.

For Performing Bioassays for H-3 (absorption thru skin and inhalation), C-14, P-32 (urinalysis) or other isotopes:

Please provide the information listed above as applicable to the isotope being measured such as the equipment, procedures, the method of counting, action or investigational levels, MDA, frequency of monitoring and method of converting the result to a dose to the individual.

When to perform Bioassays

Personnel Monitoring Requirements (internal exposure)

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 Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (b). Suitable and timely measurements used for determination of such internal exposures shall be performed as specified by Section 20.1204.

If you have a new program, you must perform bioassays to establish that your employees are not getting 10 % of the annual limit by monitoring them for a year and submitting the results for a new license amendment. If your program deals with small quantities of material, and you do not wish to have a program, submit a justification for not having a bioassay program. Please keep in mind the issue of company liability and demonstrating their employees are working safely.

References

Reg. Guide 8.9 "Acceptable Concepts, Model, Equations and Assumptions for a Bioassay Program".

Reg. Guide 8.20 "Application of Bioassay for I-125 and I-131."

NUREG – 1556, Volume 7, Appendix Q.

ANSI HPS N13.14-1994, "Internal Dosimetry Programs for Tritium Exposure- Minimum Requirements".

US NRC, Code of Federal Regulations, 10 CFR 20.1204.

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.

ICRP 30, Part 1, Limits for Intakes of Radionuclides by Workers, "Metabolic Data for Phosphorous".

Appendix F

Checklist For Effluent and Environmental Monitoring for Stack Releases

1. Specify the isotopes involved and their chemical form.
2. Indicate which room at the facility the isotopes will be released (room number/name/location).
3. Specify the approximate amount of activity anticipated to be released for the isotope(s) involved.
4. Provide the regulatory limits of the isotopes involved to be released to the air.
5. Provide information on the release stack, i.e. the distance from the exhaust vent to the nearest air intake vent, stack height, roof access, a diagram of air duct and vent locations, and confirm it has an independent exhaust stack.
6. To demonstrate compliance and knowledge of the regulatory release limits, provide calculations of the amount released and how you will be able to stay within the regulatory limits.
7. Please specify how the effluents will be monitored by specifying the equipment used, and the frequency of monitoring.

Note: For radioiodinations refer to **Appendix K**.

Appendix G
Checklist for In-Vivo Procedures with Small Animals

Provide the following:

- (1) A description of the animal housing facilities (room number/name, overall and room diagram, posting).
- (2) A copy of the radiation safety instructions provided to animal caretakers 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 (exposure rates at background and wipes < 200 dpm/100cm² is usually 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 Item 12 of the licensing application.

Appendix H

Survey Frequencies for Laboratories

To assure consistency in requirements for routine surveys at small, medium and large laboratories, follow the general guidelines specified below.

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:

<u>QUANTITIES IN USE</u> *	<u>FREQUENCY</u>
Less than 1 mCi (less than 10 mCi H-3, C-14 only)	Monthly (or after each use if used less than monthly)
1 mCi to 10 mCi (10 mCi to 100 mCi H-3, C-14 only)	Weekly (or after each use if used less than weekly)
More than 10 mCi (more than 100 mCi H-3, C-14 only)	Daily (or after each use)
Radio iodinations (or other volatile reactions)	Daily (or after each use)

* This refers to stock containers, not what is removed for 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

This checklist serves to identify information that should be included in an application for approval of proposed procedures to dispose of radioactive waste (licensed material prescribed in Sec. 20.2002) via decay-in-storage (DIS).

1. Describe the waste to be disposed of, physical and chemical properties of isotopes to be considered for the decay-in-storage method of disposal. Nuclides with half lives of greater than 90 days will not be considered.
2. Submit a description and diagram of the area where all waste containing licensed material will be held in storage. Be sure to include provisions for shielding, security, posting and labeling.
3. To ensure that doses are maintained ALARA (per 10 CFR 20.2002), provide expected dose rates in adjacent uncontrolled areas 10 CFR 20.1301 for dose limits to the public).
4. Describe areas that will be surveyed including areas adjacent to the waste storage area(s) at specified intervals, as part of routine area survey procedures.
5. Provide procedures used to ensure that the radioactive waste has decayed to background levels (not statistically different from natural background levels). Include the items listed below:
 - a. Describe the inventory control system used to track each waste container inventory record should describe the isotope, activity, and date the container was sealed and placed in storage.
 - b. Storage time: As a bench mark for initially checking the waste containers for levels of decayed waste, specify a minimum of seven (7) or ten (10) half lives of the longest lived radioactive material in the container.
 - c. Waste survey procedures: The procedures should ensure appropriate survey instrumentation for the isotopes of concern, set on the most sensitive scale with no interposed shielding, and the waste container measured/surveyed in a low background area. Surveys should include all surfaces of each container to be released for all high energy beta (> 200 keV), X-ray, and gamma emitters. If no readings above background (indistinguishable from background) are detected, the whole batch may be released.

Appendix I (continued)

The suggested instrumentation is listed below:

<u>Type of Emitter</u>	<u>Type of Instrument</u>
Beta	G-M with <2 mg/cm ² window (large area probe preferred)
X-ray or Gamma	Nal crystal (thin or thick depending on energy)

6. Describe how radioactive waste and other hazardous wastes will be segregated to prevent mixing of isotopes and containers of the same age (half life) group.
7. Describe how radioactive containers with labels will be kept from being released into the regular trash once they no longer contain licensed material. The removal or obliteration of all labels or similar markings, which indicate the presence of radioactive materials. This can be done as the waste is placed in containers, with only the container labels to be removed prior to the release.
8. Describe how record keeping of all decayed waste will be made in this manner along with all surveys made relative to storage and release of decayed waste as nonradioactive waste. Confirm that the waste disposal records will be maintained pursuant to title 17, Section 30293.

Appendix J

Package Receiving and Opening Procedures

All labeled packages must be monitored within 3 hours of delivery. If delivered after hours, must be monitored within 3 hours beginning next working day unless it contains gas or is special form (see 10 CFR 20, section 20.1906).

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 cm², 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 cm², 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 cm², 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. You must immediately notify [required by 20.1906 (d)] the final carrier and the regulatory agent if:
 - a. Removable external surface contamination \geq 2200 dpm/100 cm²
 - b. Radiation level at any point on the external surface \geq 200 mrem/hr
or,
 - c. Radiation level at one meter from the package \geq 10 mrem/hr.

Appendix K

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 using remote handling tools such as tongs when appropriate and lead shield around the source container.
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 lfpm 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 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. When one exceeds ___ % then they can remove the built up filter and move the lesser one in front and put a new one in the back.
11. Confirm the iodination fume hood has an independent exhaust stack.

Appendix L **Records to be Maintained**

This is a list of records that should be maintained as a minimum. Please refer to 10 CFR 20 Subpart L and Title 17 CCR sections 30256, 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