LICENSING GUIDELINES FOR SMALL LABORATORIES

For New, Renewal or Amendment Applications

(RIA KITS ONLY OR TOTAL ACTIVITY < 10 mCi, NO IODINATIONS)

This is a general guideline to assist those applicants wishing to obtain licensure for laboratories. All forms and checklists are available at: www.dhs.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-J) 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 at: 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 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). The use of radioactive iodine will be limited to labeled compounds only.

c. **Possession Limit:** State the maximum inventory (specified in units of microcuries or millicuries) 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.

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.

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 from our RHB website 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). A RSO Duties and Responsibilities form should be signed by the proposed RSO (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. Specify the quantity, manufacturer and model number of the survey meter(s) and the probe(s). 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 GM type survey meter with a pancake probe (or built in) with a window thickness not exceeding 2 mg/cm 2 is recommended for direct surveys. For C-14, a GM ratemeter with an 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 GM meter with a thin sodium iodide detector (scintillation probe) for adequate efficiency.

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.

c. Commit to having an adequate number of survey meters and instruments commensurate with the size and scope of the program.

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.

b. Commit to using NIST traceable sources and to follow the manufacturer's recommendation for calibration and repair. 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; Thermoluminesent 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.

Bioassay programs are generally not required for small laboratories.

Item 9. Facilities and Equipment:

a. Provide a facility diagram (overview and smaller 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 RHBSacramento 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 orientation and annual refresher training for occupational workers on the Radiation Safety Program (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 appropriate for the nuclide(s) and quantities likely to be received (see Appendix J for package

receipt procedures). Perform an exposure rate survey if the package is found delivered damaged or leaking (see 10 CFR 20.1906 (b)).

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 where readings were taken. These surveys are for both direct meter and area wipes. An action level of 200 dpm per 100 cm 2 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. 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.

Item 11. Effluent and Environmental Monitoring: Provide procedures if applicable.

a. Sanitary sewer releases: Commit to not exceeding the limits in 10 CFR 20.2003. Provide sample calculations.

b. Stack effluent:

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.

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 licensed being modified, suspended or revoked by the Department per Title 17, section 30205 (b)(1).