NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sontra Medical	3. License Number 20-30323-01
2. 767C Concord Avenue Cambridge, Massachusetts 02138-1044	4. Expiration Date September 30, 2001
	5. Docket or Reference No. 030-34191

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Hydrogen 3	A. Any	A. 50 millicuries
B. Carbon 14	B. Any	B. 25 millicuries
C. Phosphorus 32	C. Any	C. 20 millicuries
D. Sulfur 35	D. Any	D. 20 millicuries
E. Iodine 125	E. Any	E. 20 millicuries

9. Authorized use

A. through E. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. A. Licensed material may be used only at the licensee's facilities located at 767C Concord Avenue, Cambridge, Massachusetts.

B. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: (1) the licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and (2) the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 has been notified in writing that activities authorized by the license will be initiated.

In accordance with the requirements set forth in 10 CFR 30.36(b), 40.42(b), and 70.38(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

11. A. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
Michael V. Pishko, Ph.D.	H-3; C-14; S-35; and I-125
Holly L. Veno	H-3; C-14; P-32; and S-35

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B. The Radiation Safety Officer for this license is Michael V. Pishko, Ph.D.

12. Licensed material shall not be used in or on human beings.

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated June 21, 1996
B. Letter dated August 7, 1996
C. Letter dated September 9, 1996

Date SEP 20 1996

For the U.S. Nuclear Regulatory Commission

By ORIGINAL SIGNED BY:
PENNY A. LANZISERA

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

SEP 20 1996

License No. 20-30323-01
Docket No. 030-34191
Control No. 123369

Michael Pishko, Ph.D.
Radiation Safety Officer
Sontra Medical
767C Concord Avenue
Cambridge, MA 02138-1044

Dear Dr. Pishko:

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Until your license is terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:

   a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and

   b. you have notified the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.

3. Notify NRC, in writing, within 30 days:

   a. when an authorized user or Radiation Safety Officer, permanently discontinues performance of duties under the license or has a name change; or

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b. when the mailing address on the license changes (no fee is required if the location of byproduct material remains the same).

4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. when you decide to terminate all activities involving materials authorized under the license; or

   b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.

5. Request and obtain a license amendment before you:

   a. permit anyone to work as an authorized user under the license;

   b. change Radiation Safety Officer;

   c. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   d. add or change the areas of use, or address or addresses of use identified in the license application or on the license; or

   e. change ownership of your organization.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than the Radiation Safety Officer or a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:
PENNY A. LANZISERA

Penny Lanzisera
Division of Nuclear Materials Safety

License No. 20-30323-01
Docket No. 030-34191
Control No. 123369

Enclosures:
1. License No. 20-30323-01
2. 10 CFR Parts 2, 19, 20, 30, and 170
3. NRC Forms 3 and 313

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OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Lanzisera PL							
DATE	09/17/96		09/ /96		09/ /96		09/ /96	

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Sontra Medical

September 9, 1996

Docket No. 030-34191
Control No. 123369

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Penny Lanzisera
Division of Nuclear Materials Safety
Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Ms. Lanzisera:

This letter is in reference to your letter dated August 14, 1996. The response to your request for additional information is below.

1. All packages and contamination wipes will be evaluated for ^{3}H contamination by liquid scintillation counting. Package and contamination wipes will be evaluated for ^{14}C, ^{32}P, and ^{35}S with either a pancake probe Geiger Mueller detector or by liquid scintillation counting. Package and contamination wipes will be evaluated for ^{125}I either by direct measurement with a sodium iodide scintillation detector or by liquid scintillation counting. Wipes taken to verify that iodination areas are less than 100 dpm/100 cm^3 after iodinations will be measured with a liquid scintillation counter.

2. The source used for determining the efficiency of sodium iodide detectors used to evaluate air sampling filters is traceable to National Instruments of Standards and Technology ^{125}I source number SRM-4407L-D.

3. The unrestricted area action level for radiation survey is any measurement in excess of 0.05 milliroentgen per hour. For restricted areas, the action level is 0.05 mR/hour where no radioactivity is normally present, and any reading in excess of expected radiation levels where radioactive material is present. Sontra Medical will also ensure that the requirements of 10 CFR 20.1301, that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour, will be strictly enforced.

4. Sontra Medical confirms that surveys required after using greater than 1 millicurie of ^{32}P are documented and maintained.

5. Animal wastes that exceed 0.05 microcurie per gram of ^{3}H or ^{14}C will be disposed of as radioac' 'e wastes with a half-life of greater than 120 days by a licensed disposal facility such as ADCO Services, Inc. of Tinley Park, IL.

Please contact me if you require further information.

Sincerely,

Michael Pishko

Sontra Medical, L.P.
767 C Concord Avenue
Cambridge, MA 02138-1044
617-497-0600 phone
617-497-8330 fax

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Docket No. 030-34191
Control No. 123369

Michael Pishko, Ph.D.
Sontra Medical
767C Concord Avenue
Cambridge, MA 02138

Dear Dr. Pishko:

This is in reference to your letter dated August 7, 1996, in response to our letter dated July 12, 1996. In order to continue our review, we need the following additional information:

1. Your response to Item 3 of our letter appears to indicate that all package and contamination wipes for H-3 and C-14 are counted on a liquid scintillation counter and all package and contamination wipes for I-125, P-32, and S-35 are counted with either a low energy gamma scintillator or a pancake geiger-mueller. Please confirm. Also, please confirm the method of evaluation for I-125 wipes taken after iodinations since your letter states that iodination areas will be decontaminated to less than 100 dpm/100 cm^2 and your application states that the MDA of the low energy gamma scintillator for I-125 is 400 dpm/100 cm^2.

2. Please provide the identification of the source used for efficiency determination of the sodium iodide detector used to evaluate air sampling filters.

3. In response to Item 6 of our letter, you appear to indicate that your radiation survey action levels for unrestricted and restricted areas is 5 mR/hr. Based on the total activity you are requesting, this appears high. Please re-evaluate your action levels and provide both an unrestricted area action level and a restricted area action level consistent with your license request. Also, please note that, in accordance with 10 CFR 20.1301, each licensee shall conduct operations so that the dose in any unrestricted area does not exceed 2 millirem in any one hour and the total effective dose equivalent to individual members of the public does not exceed 100 millirem.

4. Please confirm that surveys required after using greater than 1 millicurie of P-32 are documented and maintained.

5. With regards to you animal handling procedures, describe the disposal process for animal waste that exceeds the limits in 10 CFR 20.2005 and with a half-life greater than 120 days. Also, please indicate on a facility diagram the location of the animal facility.

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We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123369. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5169.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

ORIGINAL SIGNED BY:
PENNY A. LANZISERA

Penny Lanzisera
Division of Nuclear Materials Safety

Docket No. 030-34191
Control No. 123369

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NAME	Lanzisera PL							
DATE	08/12/96		08/ /96		08/ /96		08/ /96	

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Sontra Medical

August 7, 1996

MS 16
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Penny Lanzisera
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Ms. Lanzisera:

This letter and enclosed material are in reference to Docket No. 030-34191, Control No. 123369. Thank you for your letter dated July 12, 1996. The additional information you requested is provided below.

1. The resumes of myself and Ms. Holly Veno have been modified to include the training information you requested and are enclosed. I also confirm that the training and experience of all supervisors who will use radioactive material unsupervised will be submitted to the NRC for approval.

2. I am available full-time to respond to questions or operational issues that arise during the conduct of Sontra Medical, L.P.'s radiation safety program and related regulatory requirements.

3. A Beckman LS 6000SC liquid scintillation counter will be used for surveys wipe for ^{3}H and ^{14}C. A Ludlum Model 44-3 low energy gamma scintillator and a Ludlum Model 44-9 Pancake G-M detector with a Ludlum Model 14C survey meter will be used for counting packages and also for survey wipes. Ludlum Measurements, Inc. (license no. LO1963) will be used for calibrations.

4. We will follow the guidance of Regulatory Guide 8.20, *Applications of Bioassay for I-125 and O-131*. We have incorporated some of this guidance into our iodination guidelines of the Radiation Safety Guide. A copy of the revised guidelines is attached.

5. Our policy for procedures such as protein iodinations that may release volatile or gaseous radioactive materials to restricted and unrestricted areas include:

   Air sampling

   We may use the air sample analysis to estimate intakes of airborne radionuclides for both workers and the general public. Workers will also be evaluated for intakes through thyroid bioassay. These intakes will be used to calculate the committed effective dose equivalent portion of the total effective dose equivalent as defined in 10 CFR 20. Worker intakes may be estimated from breathing zone air samples obtained down stream of the charcoal absorber filtration incorporated in the iodination fume hood. Intake estimates calculated from the ratio of the sample

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concentration to the applicable derived air concentrations and effluent concentrations of 10 CFR 20 Appendix B, Tables 1 and 2, respectively.

Air samples will be obtained using a pump taking suction at a known velocity from the worker's breathing zone and from the charcoal-filtered effluent air through carbon impregnated filters. The researcher performing the iodination will start and stop the sampling interval unique to that particular iodination. The filters will be given to the RSO so radioactivity analysis may be performed. The filters will be counted with a Baird Atomic Polyspec Research Spectrometer connected to a NaI scintillation detector with a predetermined background and ^{125}I counting efficiency. An example of the air sample analysis worksheet is attached.

Radiological surveys

Persons performing iodinations must survey the iodination facility before and after the iodination procedure. Surveillance is designed to discover radiation levels of concern as well as radioactive material contamination. A Ludlum Model 3 surveyor meter equipped with a Ludlum Model 44-3 NaI scintillation detector will be used to perform radiation level surveys. Wipe tests counted with the NaI detector will be used to evaluate the facility for radioactive material contamination. Unexpected radiation levels will be investigated and sources of unexpected radiation levels will be removed or shielded to reduce exposure. ^{125}I contamination in excess of 100 dpm/100 cm^2 will be decontaminated down to below that surface contamination level. These surveys will be documented for each day an iodination procedure is performed. The RSO shall be given a copy of the survey upon its completion. An example survey sheet is attached.

6. Our radiation safety program requires that users perform and document radiological surveys for 1) animal work using radioisotopes, 2) iodinations, 3) radioactive package receipt and 4) for waste disposal. In addition the RSO or a private consultant will perform monthly surveys of all radioactive materials areas. Users are also instructed to perform radiation and contamination surveys of their work areas following any other use of radioisotopes. All radiological survey records will be maintained for the duration of the Material License.

   With all surveys, the surveyor must contact the RSO should any unexpected radiation levels be encountered. The RSO must be notified any time the radiation level in any area accessible to individuals could result in an individual receiving a dose equivalent in excess of 5 millirem in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates. The RSO will investigate the cause of the unexpected and/or excessive (i.e., >5 mR/hr) radiation levels and either remove the source or shield or otherwise reduce the intensity of the radiation.

7. Description of the animal's housing facilities.

   Sontra's animal housing facilities consist of two rooms. The animal housing room is a 9' by 12' room with a single locked entrance opening into the cage washing room. The housing room has a dedicated HVAC system to maintain humidity and temperature within PHS guidelines. The floor of the housing room is water-proof and designed to contain a liquid spill within the room. The other room in the facility

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is dedicated for cage washing. This room has a large stainless steel sink with drainage into the sewer system. The floor of the wash room is water-proof and designed to contain liquid spills. The cage washing room opens into Laboratory 1, which has a locked entrance.

Animal caretaker instructions

A radiation safety procedure for the use of radioactive materials with animals has been attached. This will used to train and qualify animal caretakers and researchers. We expect that for the foreseeable future, the researcher will provide for all animal care when radioisotopes have been administered to those animals.

8. We have revised our instructions for radioactive materials receipt and survey to include specific instructions that gloves be worn while opening packages of radioactive materials. A copy of this revision for Appendix 4 of our Radiation Safety Guide is attached.

9. Sontra Medical confirms that we will follow all applicable Department of Transportation regulations associated with shipping radioactive materials. Relevant regulations include those of Title 49 of the Code of Federal Regulations.

If you have any questions regarding this letter or the application, please call me at 617-497-0600.

Sincerely,

Michael V. Pishko
Sontra Medical, L.P.

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Sontra Medical

Michael V. Pishko, Ph.D.
[redacted]

- Trained at the University of Texas at Austin in the use of radiochemicals. Fall 1990. This consisted of 8 hours of formal classroom training on a) principles and practices of radiation protection, b) radioactivity measurements, standardization, and monitoring techniques and instruments, c) mathematics and calculations basic to the use and measurement of radioactivity, and d) biological effects of radioactivity.
- Iodinated proteins and used in in vitro experiments, used ^{3}H and ^{14}C labelled small molecules in both in vitro and in vivo experiments. Fall 1990-Summer 1992. Location: University of Texas at Austin. Maximum quantities handled: ^{3}H = 250 microCi, ^{14}C = 250 microCi, ^{125}I = 1 mCi.
- Trained at Massachusetts Insititute of Technology in the use of radiochemicals. February 1995. This consisted of 4 hours of formal classroom training on a) principles and practices of radiation protection, b) radioactivity measurements, standardization, and monitoring techniques and instruments, c) mathematics and calculations basic to the use and measurement of radioactivity, and d) biological effects of radioactivity.
- Iodinated proteins and used in in vivo experiments, used ^{3}H and ^{14}C labelled small molecules in both in vitro and in vivo experiments. Fall Feb. 1995-Jan. 1996. Location: Massachusetts Institute of Technology. Maximum quantities handled: ^{3}H = 250 microCi, ^{14}C = 100 microCi, ^{125}I = 1 mCi.

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Holly L. Veno
Sontra Medical, L.P.

- Trained at Boston University on the use and precautions of ^{3}H. Training included formal coursework -- 3 hour class. Information included: Protection from ^{3}H; measuring and monitoring ^{3}H and other radioisotopes; math calculation; and effects of ^{3}H exposure

- Trained at University of New Hampshire on use and precautions of ^{32}P and ^{35}S. Formal coursework -- 3 hour class and on-the-job training. Information included: protection and use; monitoring and measuring; calculations; and effects of ^{3}H exposure.

- Total maximum activity:
    - ^{3}H 1 millicurie
    - ^{32}P 500 microcuries
    - ^{35}S 500 microcuries

- Distilled water from blood samples that had been labeled with ^{3}H and then analyze the isotope content of the samples at BU, max. amount of 1 millicurie over a 2-year period.

- Taught undergraduate students in a Microbial Genetics Laboratory on the technique of labeling and working with DNA that was labeled with ^{32}P at University of New Hanmpshire; maximum amount at 250 microcuries over a 1-year period.

- Used ^{32}P to label isolated bacterial DNA and to run the radiolabeled DNA on an agarose gel for further detection at University of New Hampshire over a 1-year period for a max. amount of 250 microcuries.

- Used ^{35}S to radiolabel bacteria that could then be used in assays to determine the adherence of the organism to different mammalian cells at University of New Hampshire a maximum amount of 500 microcuries over 3 years was handled.

Guidelines for Iodinations

Iodine in the unbound state volatizes readily and is efficiently taken into the body by inhalation or absorption through the skin. Approximately 30% of the activity taken in remains in the thyroid. I-125 has an effective half-life of about 42 days. Thus, the predominant concerns with handling unbound iodine are preventing inhalation through the use of sufficient ventilation, and preventing absorption through the skin using protective clothing. Equally important, Sontra Medical must measure radioiodine activity released to the environment. All radioiodine work therefore must be performed under strict controls.

1. Always work in a well-ventilated hood. A Lucite inner hood (mini-hood) with a charcoal filter on its discharge may be used. Monitoring of the breathing zone air and the hood air exhaust will be performed. Charcoal impregnated filters or activated charcoal canisters are used for air sample collection of iodines.

2. Written procedures for iodinations are approved and maintained by the Radiation Safety Officer. Procedures must be designed to minimize the opening of any vials through the use of syringe injection of material through septum-topped vials. All containers of the radioactive material must be sealed in some manner, e.g., rubber stoppers, plastic wrap or parafilm.

3. Conduct a dry-run of the procedure to minimize the chance of error when activity is used.

4. A baseline thyroid measurement must be performed for anyone participating in the iodination.

5. Wear a whole body personnel radiation dosimeter. Wear an extremity monitoring finger ring when working with $\geq$ 1 mCi.

6. Wear the proper protective clothing, safety glasses and two layers of protective gloves. Iodine diffuses rapidly through vinyl and rubber so replace the outer protective gloves immediately when they become contaminated. Keep the inner pair of gloves free of contamination.

7. Have a properly calibrated survey meter equipped with a NaI detector on and readily available for quick contamination checks. Be careful not to contaminate the instrument itself.

8. Avoid handling the vials directly. Use remote handling devices such as tongs or forceps.

9. To decontaminate equipment or surfaces, use a solution which efficiently removes the contamination without releasing iodine to the atmosphere.

10. All waste must be sealed in double layers of plastic and disposed of immediately.

11. The activity concentration of the exhaust must be monitored to assure compliance with NRC regulations concerning release of radio-iodine to the environment.

12. Clean and check all the working surfaces and equipment for contamination immediately after the procedure is finished. Take contamination wipes and count them with your samples.

13. Obtain a thyroid iodine burden measurement within 72 hours of the iodination.

Sontra Medical will follow the guidance of Regulatory Guide 8.20, *Applications of Bioassay for I-125 and I-131*. As a minimum, thyroid bioassay will be necessary when an individual handles in an open form unsealed volatile or dispersible quantities of radioactive iodine in excess of 1 mCi in a 3 month period (in excess of 10 mCi when bound to a nonvolatile agent).

Thyroid bioassays will be performed for baseline measurements, routinely, for emergency purposes, when iodinations of employment ceases for an employee, and diagnostically. Routine thyroid bioassay will be performed within 6 to 72 hours post-iodination. The action levels and responses for our thyroid bioassay program are as follows:

For a thyroid burden measurement of 0.12 µCi of ^{125}I, actions include:

1. Investigation of the operations involved to determine the causes of exposure and to evaluate the potential for further exposures.
2. Worker restriction from iodinations until the source of exposure is discovered and corrected.
3. Corrective actions against further exposures.
4. A repeat of bioassay within two weeks of the first.
5. Applicable reports to regulators.

For a thyroid burden measurement of 0.5 µCi of ^{125}I, actions required include:

1. Investigation of the operations involved to determine the causes of exposure and evaluate the potential for further exposures.
2. Worker restriction from iodinations until the source of exposure is discovered and corrected.
3. Corrective actions against further exposures.
4. A repeat of bioassay within two weeks of the first.
5. Applicable reports to regulators
6. Appropriate medical consultation for the exposed individual.
7. Weekly repeated bioassays until the thyroid burden measurement is less than 0.12 µCi.

IT CANNOT BE EMPHASIZED TOO STRONGLY THAT NEAT, CAREFUL WORK HABITS WILL MINIMIZE BOTH CONTAMINATION PROBLEMS AND UNNECESSARY EXPOSURE TO PERSONNEL.

Sontra Medical

Worksheet for Environmental Monitoring for Radioiodine

Date of sample: _____ Date of counting: _____

U_S or U_B = $\frac{cpm_s - cpm_b}{R \epsilon 2.22E9 \cdot F \cdot T}$ % DAC = $\frac{U_S}{DAC}$ % DEC = $\frac{U_S}{DEC}$ ϵ = $\frac{cpm_r}{dpm_r}$

$U_S \equiv$	Activity Concentration in Effluent Stack in μCi/ml
$U_B \equiv$	Activity Concentration in Breathing Zone in μCi/ml
$cpm_s \equiv$	Counts Per Minute in Sample
$cpm_b \equiv$	Counts Per Minute in Background
$cpm_r \equiv$	Counts Per Minute From Reference Source
$dpm_r \equiv$	Disintegrations Per Minute From Reference Source (48,840 dpm)
$R \equiv$	Retention of Air Sample Media (0.98 for 2 filters, 0.85 for 1)
$\epsilon \equiv$	Efficiency of Counting Instrument in counts/disintegration
2.22E9 $\equiv$	Conversion Factor μCi/dpm·ml/l
$F \equiv$	Flow Rate of Sample Collector (11 l/m Stack; 2 l/m Breathing Zone)
$T \equiv$	Time Sample Collected in Minutes
DAC $\equiv$	Nuclide Derived Air Concentration, 10 CFR 20, App. B, Table 1, Col. 3
DEC $\equiv$	Nuclide Derived Effluent Concentration, 10 CFR 20, App. B, Tbl. 2, Col. 1

U_S DEC = 3E-10 μCi/ml (^{125}I) 2E-10 μCi/ml (^{131}I) ϵ = cpm_r/48840 dpm = ___

cpm_s = ___ cpm
cpm_b = ___ cpm
cpm_r = ___ cpm
R = ___
ϵ = ___ c/d
F = ___ l/m
T = ___ m

$U_S = \frac{cpm_s - cpm_b}{R \epsilon 2.22E9 \cdot F \cdot T}$ = _____ μCi/ml % DEC = $\frac{U_S}{DEC}$ = ___ %

U_B DAC = 3E-8 μCi/ml (^{125}I) 2E-8 μCi/ml (^{131}I) ϵ = cpm_r/48840 dpm = ___

cpm_s = ___ cpm
cpm_b = ___ cpm
cpm_r = ___ cpm
R = ___
ϵ = ___ c/d
F = ___ l/m
T = ___ m

$U_B = \frac{cpm_s - cpm_b}{R \epsilon 2.22E9 \cdot F \cdot T}$ = _____ μCi/ml % DAC = $\frac{U_B}{DAC}$ = ___ %

Sontra Medical, L.P.
Iodination Survey Log

Name of Researcher: _____

Date: _____

Activity: _____mCi

Instructions:

After wiping each surface location, place the wipe at the probe face and record the highest scale value shown by the survey meter. Next, place the NaI scintillation detector in contact with the floor waste containers and record the CPM value in the bottom table.

Surface Location	Wipe Results† (cpm)	
	Before?	After?
apron of hood		
inside of hood behind sash		
floor directly below apron		

†if results are not greater than background, record the letters "BG" in the appropriate boxes.

Direct Probe Survey	Survey Results† (cpm)	
	Before?	After?
cold trash container		
radioactive waste container		

†if results are not greater than background, record the letters "BG" in the appropriate boxes.

SURVEY CHECKLIST (Initial Each Responsibility)

Obtain your thyroid bioassay from RSO within 72 hours _____

Collect the air samples and give them to the RSO in the envelopes _____

File this survey with the RSO immediately after your iodination _____

Reviewed by: _____ Date Filed: _____

RSO

Sontra Medical, L.P.
The Use of Radioactive Materials With Animals
Radiation Safety Procedures

I. Prerequisites

A. Unless specifically authorized by the Radiation Safety Officer, the researcher will be responsible for animal care when the animal protocol requires the use of radioactive materials.

B. The Radiation Safety Officer (RSO) must be informed of all uses of radioactive material. The RSO must review the animal protocol and approve the radiation safety elements to be used during the work.

C. The use of radioactive materials is allowed only in areas specifically designated by the RSO.

D. Only trained and registered radiation workers may perform work with radioactive materials and animals.

E. The RSO must approve of actual animal facility radiological controls prior to the start of work and after any significant changes to those controls.

F. All radioactive materials must be maintained under strict security in labeled containers.

G. All other radiological controls specified in the Sontra Medical Radiation Safety Guide must be practiced in addition to those listed here.

II. Preparatory Steps

A. Place spill trays or absorbent materials such as diapers where contaminated liquids will be generated.

B. Segregate work areas where radioactive materials will be used with animals from other areas with yellow and magenta tape.

C. Label all items that may become contaminated, including animal cages, with yellow and magenta tape.

D. Obtain a functional radiation survey meter.

E. Don protective clothing:

1. Surgical scrubs,
2. Lab coat,
3. Two pair of surgical gloves
4. Facial protection such as a face shield or safety glasses and surgical mask to protect the eyes, nose and mouth from aerosols.

F. Provide for radioactive waste disposal, first with shatter-proof jars which are convenient to the animal work, and second for larger volumes. Large volumes of waste disposal must be coordinated with the RSO.

III. General contamination precautions:

A. Attempt to control liquids and sprays, particularly during surgical procedures as they can spread contamination easily and quickly.

B. Change gloves often to avoid cross-contamination of clean surfaces.

C. ^{14}C, ^{35}S and ^{32}P may be monitored with a pancake probe Geiger-Mueller detector; ^{125}I must be monitored with a NaI scintillation detector; and ^{3}H may only be monitored by counting wipe tests with a liquid scintillation counter.

D. Take special care to avoid needle sticks or other wounds with radioactively contaminated objects.

IV. Post-experiment clean-up:

A. Wrap sacrificed animals in the absorbent materials used to protect work surfaces from contamination and place in double plastic bags for freezing. The absorbents will reduce the chance of contaminated body fluid leakage and contamination.

B. Wash low levels of contamination from equipment, including animal cages, in the sink. Document this disposal verifying that it is within posted sink disposal limitations.

C. Wash all work surfaces with spray cleaner.

D. Place contaminated equipment which will be used for subsequent radioactive work in labeled plastic boxes or other interim storage.

E. Perform radiation survey and contamination wipe tests in accordance with attached survey sheet. This must be done at least at the end of every day that radioactivity work with animals is undertaken.

F. Return radioactive stock vials to their secured storage location and deduct used radioactivity from inventory records.

V. Waste Disposal

A. Small amounts of water dispersible radioactivity may be washed down the sink drain to the sanitary sewage. Verify the acceptable levels of radioactivity on the sink card at the sink prior to disposal.

B. Liquids above acceptable sink disposal values must be stored for final disposition as approved by the RSO.

C. All animal wastes will be incinerated by a licensed disposal facility of contaminated waste with ^{14}C or ^{3}H below 0.05 μCi/gram. Other animal

wastes may be decayed in storage and disposed of as non-radioactive animal waste.

D. Solids, including animal bedding, that cannot be disposed of with animal waste must be stored for disposal according to RSO instructions.

E. Sharps waste should be decontaminated prior to disposal as non-radioactive waste. For sharps waste that cannot be decontaminated, decay in storage or disposal with a licensed radioactive waste disposal company is required.

F. Document the activity of all wastes disposed of on the appropriate waste record.

VI. Animal Husbandry

A. Registered radiation workers responsible for the animal experiments must provide that animal husbandry following administration of the radioactive material.

B. Don protective clothing, e.g., lab coat and double lab gloves.

C. Wash before and after removing gloves.

D. Animal cages must be properly labeled to warn of the potential of radioactive material contamination.

E. Animal handling time must be minimized.

F. Animal bedding will be disposed of in separate radioactive waste containers.

G. All animal cages will be decontaminated and radiologically surveyed in accordance with the attached survey sheet.

Radioactive Material Receipt and Opening Procedure

1. Radioactive material packages are separated from others upon receipt. If a package contains $\geq$ 1 mCi of P-32 or I-125, extremity dosimetry must be worn by the person performing radioisotope receipt and delivery.

2. If the shipment appears damaged, ask the carrier to remain and record any signs of damage to the package or its contents.

3. A radiation and contamination survey must be made within 3 hours of radioactive material receipt if received during normal working hours, or not later than 3 hours form the beginning of the next working day for receipt after working hours.

4. Radioactive material receipt and survey is documented on the Radioisotope Receipt and Delivery form. Radiation levels are measured with a G-M survey meter, and tritium wipe tests are counted with a liquid scintillation counter.

5. Wipe approximately 300 cm^2 (about 7" x 7") of the package external surface, count the wipes for contamination, and record the results. The package must be $\leq 10^{-5}$ $\mu Ci/cm^2$.

6. Measure the highest radiation levels at the package surface and at 1 meter from the package surface, and record the results. Acceptable radiation levels are listed on the receiving form.

7. Packages of radioactive material are to be opened only in the designated radioisotope laboratories unless there is evidence of physical damage. If there is evidence of damage, the inner contents must be surveyed with the survey results recorded, and the RSO notified. Whenever a radioactive material package is opened, the contents must be treated as radioactively contaminated and gloves must be worn while handling the package and its contents until verified they are free of radioactive material contamination by radiological survey.

8. If all wipe tests are $\leq 10^{-5}$ $\mu Ci/cm^2$ and the radiation levels are acceptable, the radioisotope may be delivered, otherwise contact the RSO to check 10 CFR 20.1906 for appropriate organizational response.

9. Do not leave radioactive materials unattended; delivery immediately to the user for proper storage. If the user cannot be found, contact the user's lab supervisor for proper disposition.

10. After verifying package and packing material radiation levels are at background levels and all wipe tests are less than 10^{-5} $\mu Ci/cm^2$, the package and packing materials may be discarded in regular trash; otherwise the package and/or packing materials must be discarded with solid radioactive waste.

Sontra Medical, L.P.
Iodination Survey Log

Name of Researcher: _____

Date: _____

Activity: _____mCi

Instructions:

After wiping each surface location, place the wipe at the probe face and record the highest scale value shown by the survey meter. Next, place the NaI scintillation detector in contact with the floor waste containers and record the CPM value in the bottom table.

Surface Location	Wipe Results† (cpm)	
	Before?	After?
apron of hood		
inside of hood behind sash		
floor directly below apron		

†if results are not greater than background, record the letters "BG" in the appropriate boxes.

Direct Probe Survey	Survey Results† (cpm)	
	Before?	After?
cold trash container		
radioactive waste container		

†if results are not greater than background, record the letters "BG" in the appropriate boxes.

SURVEY CHECKLIST (Initial Each Responsibility)

Obtain your thyroid bioassay from RSO within 72 hours _____

Collect the air samples and give them to the RSO in the envelopes _____

File this survey with the RSO immediately after your iodination _____

Reviewed by: _____ Date Filed: _____

RSO

Sontra Medical, L.P.
The Use of Radioactive Materials With Animals
Radiation and Contamiration Survey

For radiation survey, scan all surfaces where radioactivity was used or may have been transferred for radiation levels above background. Move the detector slowly and maintain the probe no further than 1 cm from surface scanned. Document the results below.

For contamination survey, take wipe tests in all areas where radioactivity was used or where it may have been transferred during work. Pay particular attention to work benches, floors, the sink, and laboratory equipment which may have become contaminated. Wipe an area of 100 cm^2 with each wipe. Court the wipe tests by liquid scintillation counting and maintain the printout with this survey record.

Survey Documentation: **Waste Disposal:**

Date:	_____	Radioactive carcasses tagged & double bagged:	_____
Researcher:	_____	Radioactive carcasses in designated freezer:	_____
Radionuclide:	_____	Animal bedding in appropriate storage drum:	_____
Animal:	_____	Liquid wastes as per RSO instructions	_____
Total Activity Used:	_____		_____

Radiation Survey Results:

Initial Appropriate:	No radiation levels above background	_____
	Radiation levels above background eliminated	_____
	Final radiation levels not above background	_____

Radiation Survey Results:

Initial Appropriate:	No radioactive contamination > 200 dpm/100 cm^2*	_____
	Radioactive contamination decontaminated	_____
	Final radioactive contamination <200 dpm/100 cm^2*	_____
	Attached LSC Printout	_____

Comments:

Provide RSO a copy of this survey and maintain the original in personal file. *100 dpm/100 cm^2 is required with ^{125}I.

Sontra Medical
Radioisotope Receipt and Delivery

Purchase Order # _____ Date of Receipt _____

Isotope Ordered _____ Isotope Received _____

Activity ordered _____ Activity Received _____

External Package Contamination: _____ $\mu Ci/cm^2$

Radiation Level at Surface: _____ mR/hr

Radiation Level at 1 Meter: _____ mR/hr
(Transport Index)

Packages above the following limits are held for notification to vendor, shipper, and NRC. Contact the RSO immediately.

Contamination: $\leq 10^{-5}$ $\mu Ci/cm^2$
Radiation levels:

White I Label	0.5 mR/hr @ surface	background @ 1 meter
Yellow II Label	50 mR/hr @ surface	1 mR/hr @ 1 meter
Yellow III Label	200 mR/hr @ surface	20 mR/hr @ 1 meter

Damaged Package Survey

Description of Damage:

Contamination level: _____ $\mu Ci/cm^2$
Radiation level: _____ mr/hr

Date and Time of Delivery to User _____

User Signature _____

TREAT ALL RADIOACTIVE MATERIALS PACKAGE CONTENTS CONTAMINATED UNTIL PROVEN OTHERWISE - WEAR GLOVES WHILE HANDLING THE SUSPECT PACKAGE AND ITS CONTENTS.

JUL 12 1996

Docket No. 030-34191
Control No. 123369

Michael Pishko, Ph.D.
Sontra Medical
767C Concord Avenue
Cambridge, MA 02138

Dear Dr. Pishko:

This is in reference to your application dated June 21, 1996. In order to continue our review, we need the following additional information:

1. The resumes of the training and experience provided for yourself and Ms. Holly Veno did not include the hours of training in radiation safety or the maximum activity used per isotope. Provide a brief resume including the type (on-the-job or formal course work), location, and duration of the training. Training should cover (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring techniques and instruments, (c) mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The description of the use of licensed materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use. Also, confirm that the training and experience for all supervisors who will use radioactive material unsupervised (by an individual listed on your NRC license) will be submitted to the NRC for approval.

2. Describe your overall availability to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements (i.e, full time or part time).

3. Identify the instrumentation used for counting package and survey wipes. Also, provide the name and license number of at least one survey instrument calibration facility that you may use for meter calibrations.

4. Describe your action levels for your thyroid bioassay program including the type of action taken when action levels are exceeded.

5. Describe your procedures for complying with Sections 20.1203, 20.1204, and 20.1302 of 10 CFR Part 20, for procedures such as protein iodinations that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys (e.g., environmental or breathing zone), frequency of surveys, and the individuals who will perform the surveys (e.g., radiation safety

officer or investigator), equipment to be used, and the procedures for evaluating the results.

6. Describe the type(s) of surveys performed by users and the record-keeping requirements for users' surveys. Appendix 4 of your application appears to address this item, however, it is unclear as to whether the appendix refers to users' surveys or RSO surveys. Also, please provide your action limit for area surveys in units of mR/hr.

7. If licensed materials are to be used in animals, please submit:

   a. a description of the animal's housing facilities, and

   b. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

8. Confirm that your package opening procedures include a requirement to use gloves when handling radioactive packages and to verify the contents of the package.

9. Confirm that you will follow all Department of Transportation regulations when shipping radioactive material.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123369. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5169.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

ORIGINAL SIGNED BY:

Penny Lanzisera
Division of Nuclear Materials Safety

Docket No. 030-34191
Control No. 123369

DOCUMENT NAME: R:\WPS\DLTR\L3030323
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Lanzisera PL							
DATE	07/12/96		07/ /96		07/ /96		07/ /96	

OFFICIAL RECORD COPY

NRC FORM 313 (6-93)
10 CFR 30, 32, 33, 34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN: 030-34191

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: LL 30323

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351 03620

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [X] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*
   Sontra Medical
   767C Concord Avenue
   Cambridge, MA 02138

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   Sontra Medical
   767C Concord Avenue
   Camgridge, MA 02138

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   Dr. Michael Pishko

   TELEPHONE NUMBER
   (617) 497-0600

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9.	FACILITIES AND EQUIPMENT.	10.	RADIATION SAFETY PROGRAM.
11.	WASTE MANAGEMENT.	12.	LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY 3M; AMOUNT ENCLOSED $ 1500

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Stephen C. Rowe, President & CEO	Stephen C Rowe	06/21/96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY			DATE		123369

NRC FORM 313 (6-93)

PRINTED ON RECYCLED PAPER

OFFICIAL RECORD COPY ML 10

JUN 26 1996

Sontra Medical

June 24, 1996

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 10406-1415

Sontra Medical, L.P. is applying for a material license. This document supports the NRC Form 313 which is attached. Please do not hesitate to contact us should you require any other information to process this application.

Sincerely,

Stephen C. Rowe
President & CEO
Sontra Medical, Inc., the
General Partner of Sontra Medical, L.P.

Sontra Medical, L.P.
767 C Concord Avenue
Cambridge, MA 02138-1044
617-497-0600 phone
617-497-8330 fax

The following information is provided to supplement the application documentation on NRC Form 313, *Application for Material License.*

5. Radioactive Material

Element & Mass No.	Chemical/ Physical Form	Maximum Possessed at Any One Time
^{3}H	Any	50 millicuries
^{14}C	Any	25 millicuries
^{125}I	Any	20 millicuries
^{32}P	Any	20 millicuries
^{35}S	Any	20 millicuries

6. Purposes for Which Licensed Material Will Be Used

Sontra Medical, LP is engaged in drug delivery research. The licensed materials above will be used *in vitro* and *in vivo* as labels in this research. The *in vivo* protocols require the use of small laboratory animals. Some of the ^{125}I experiments will require protein iodinations. Protocols using radioactive material are those common to biological and chemical laboratories in the pharmaceutical industry. Examples include cell culture, immunoassay, protein iodinations, DNA labeling, polymerase chain reaction, centrifugation, microscopy, hybridization, lyophilization, incubation, and electrophoresis. Typical protocol activity ranges are from one to 1000 μCi per experiment.

Licensed materials will only be used at our facilities at 767C Concord Avenue, Cambridge, Massachusetts. Sontra Medical will not use licensed materials in or on human beings.

7. Individual(s) Responsible For Radiation Safety Program and Their Training Experience

Michael Pishko, Ph.D. will serve as the Radiation Safety Officer. Dr. Pishko works full-time as a Scientist at Sontra Medical. He has extensive training and experience working with radionuclides, including those in this materials license application. Dr. Pishko's *Curriculum Vitae* is attached. His radiation safety training and experience with radionuclides has accumulated over six years at the University of Texas at Austin and the Massachusetts Institute of Technology. He has also received appropriate radiation safety training as tabulated below:

Location	Dates	Subjects
University of Texas	1990	Formal classroom training in the safe use of radionuclides including ^{14}C, ^{3}H, ^{125}I, ^{32}P, and ^{35}S. Subjects included proper use, handling and disposal of radioactive materials, radiation measurement methods, radiological calculations, the health hazards associated with radiation exposure, regulations, radiation physics, radiological units and quantities, radiation dose limits, health effects of radiation, ALARA, equations for radiation measurement, and emergency procedures.
University of Texas	1990-1992	On the job training in the safe laboratory use of radionuclides and radiation and radioactivity analysis. Direct experience in high activity ^{125}I iodinations, *in vivo* experiments with ^{3}H and ^{14}C, exposure reduction methods, and radiation instrumentation processes.
Massachusetts Institute of Technology	1995	Formal classroom training in the safe use of radionuclides including ^{14}C, ^{3}H, ^{125}I, ^{32}P, and ^{35}S. Subjects included Federal regulations, radiation physics, radiological units and quantities, radiation dose limits, health effects of radiation, ALARA, equations for radiation measurement, and emergency procedures.
Massachusetts Institute of Technology	1995-1996	On the job training in the safe laboratory use of radionuclides including up to 10 mCi of ^{3}H, 10 mCi of ^{14}C, as much as 40 mCi of ^{125}I, up to 5 mCi of ^{32}P, as much as 15 mCi of ^{35}S, and 5 mCi of ^{111}In. Particular expertise in high activity ^{125}I iodinations, *in vivo* experiments with ^{3}H and ^{14}C, in measurement and monitoring techniques, mathematical principals for calculating activity and biological effects of radiation.

In addition, Sontra Medical has retained William E. Irwin and Judith M. Reilly, health physics consultants from the Massachusetts Institute of Technology, as assistant radiation safety officers. They are readily available to assist Dr. Pishko in any radiological safety needs he may have.

Along with Dr. Pishko, Holly L. Veno, a full-time research associate, will be designated to supervise the use of radioactive materials. She will be assigned the capacity to manage the use of any of our licensed materials, and in any chemical or physical form. Ms. Veno's *Curriculum Vitae* is attached. She has received thorough

and comprehensive radiation safety training at the University of New Hampshire and Boston University and has had significant experience with radionuclides at those institutions, especially with ^{3}H, ^{32}P, and ^{35}S.

8. Training for Individuals Working In or Frequenting Restricted Areas

Radiation safety training will be provided to all Sontra Medical, LP employees. All Sontra Medical employees allowed access to areas where radioactive materials are present will be trained as radiation workers. The Radiation Safety Officer will ensure this training is accomplished in a timely and effective manner, either personally or through an independent consultant. Ancillary employees will be trained to recognize radiation warning signs, avoid contact with radioactive materials and loitering in radioactive materials areas, and the appropriate response to unusual conditions. The topics for radiation worker training include:

Regulations	Security of Radioactive Materials
Radiation Physics	Radiological Units and Quantities
Radiation Dose Limits	Health Effects of Ionizing Radiation
Contamination Control	Internal and External Dose Optimization
Radioactive Waste Reduction	Equations and Rules of Thumb
Emergency Procedures	Sontra Medical Radiation Safety Guide

Additional protocol-specific training, for example, for animal studies using radioactive materials and iodinations, will be provided to those authorized to perform those protocols. In addition, an annual refresher training seminar will be required of all radiation workers.

9. Facilities and Equipment

Sontra Medical, LP currently occupies approximately 3800 ft^2 of office and work space. About 2500 ft^2 in four rooms is devoted to laboratory work. One room is an animal facility, a second is a storage room, and two are biological and chemical research rooms. Each of these four rooms will be controlled for protection against radioactive materials exposure. All Sontra Medical employees will be trained radiation workers and allowed access to radioactive materials areas.

Two doors allow access to the Sontra Medical facilities. A rear door is secured to outside persons by a lock at all times except when Sontra Medical personnel exit to the loading dock. The front door is open to visitors and other people only during work hours. Individuals that enter through the front door must pass a reception area which is occupied by an employee instructed to verify a person's authorization to pass to radioactive materials areas. All rooms where radioactive materials may be stored or used may be locked to prevent unauthorized access when the room is not under the surveillance of a trained radiation worker.

The radioactive materials areas are protected from the elements in the same manner as the rest of the building. Fire detection and fire suppression systems are provided in each room. The floors in laboratory spaces are covered in waterproof and chemical resistant materials. Adequate ventilation is provided to mitigate the consequences of all radioactive, chemical and other physically hazardous activities. The main laboratory, the synthesis lab, is equipped with a fume hood. If and when iodinations are to be performed, they will be performed in this fume hood in a separate inner "mini-hood". The mini-hood will be equipped with charcoal filtration to adsorb iodine molecules, an effluents monitor and a breathing zone air sampler. Radioactive effluent and worker breathing zone air concentrations will be determined for each iodination.

At least one sink in each laboratory will be designated for disposal of radioactive liquids and readily disposable biological wastes which are determined to be below the applicable sewage disposal concentration. The laboratories are well lit, permit freedom of movement, and allow for the safe performance of work. No hand-to-mouth activities are permitted in laboratory spaces, but are allowed in office areas and the common kitchen. Thyroid burden measurements will be performed by an outside consultant using a sodium iodide scintillation detector. This detector is calibrated using a tissue-equivalent phantom with a minimum detectable activity of one nanocurie.

A floor plan is attached.

10. Radiation Safety Program

Please find included in this application package the Sontra Medical Radiation Safety Guide. This document serves as our radiation safety program and a copy will be provided to each radiation worker. Additional specific procedures may be written to augment the radiological controls contained within the Radiation Safety Guide.

11. Waste Management

Solid radioactive wastes will be collected during work in containers in the laboratories. When these containers are full, they will be emptied into 30 or 55 gallon drums in the waste storage area. Waste materials contaminated with radionuclides with half-lives less than 65 days or ^{35}S will be held for decay for at least ten half-lives, surveyed to verify that radiation measurements are indistinguishable from background levels, and then disposed of as non-radioactive waste. Waste materials contaminated with radioactive materials other than ^{35}S and with half-lives greater than 65 days will be stored until they can be disposed of by a licensed disposal vendor.

To verify that wastes that have decayed ten half-lives exhibit radiation levels at background levels, as well as for all other radiological surveys, the appropriate radiation survey meters shall be used. For beta-gamma radiation measurements a Ludlum Model 3 survey meter will be equipped with a pancake Geiger-Mueller

detector (Model 44-9). For ^{125}I measurements a second Ludlum Model 3 survey meter will be equipped with a sodium iodide scintillation detector (Model 44-3) will be used.

These and other radiation survey instruments will be calibrated by a licensed calibration facility on an annual basis. If the instruments are repaired, they will be recalibrated after the completion of the repair. A calibration record with applicable information is attached to each calibrated instrument. Calibration certificates are maintained by the Radiation Safety Officer. The Geiger-Mueller detectors will be calibrated with a minimum detectable activity of 1600 disintegrations per minute for ^{14}C and ^{35}S and 200 disintegrations per minute for ^{32}P. The sodium iodide scintillation detector will be calibrated with a minimum detectable activity of 400 disintegrations per minute for ^{125}I.

All reference to radioactive materials, for example labels or tape, must be removed or completely obliterated prior to final disposal. A record of the date waste was put in storage, the date it was removed from storage, the date disposed as regular trash, the survey instrument used, the background dose rate, and the name of the surveyor will be maintained for all decay in storage waste.

A locked waste disposal storage area (see attached floor plan) will be designated for the storage of low level radioactive waste. Routine radiation and contamination surveys will be performed in this storage area and visual inspection of the drums will not be problematic. The waste storage facility is within the core lab space of the building protected from weather at all times, and locked at all times when unattended. General room air ventilation is adequate for the storage of these wastes. The storage room is equipped with a fire detection and extinguishing equipment.

Solid radioactive waste will be stored in 55 or 30 gallon steel drums which are currently the accepted packaging for transportation and final disposal. Waste volume reduction will be through compaction and planned waste avoidance. The waste should pose no hazard to the container's integrity and the containers should last indefinitely. The door to the storage area will be posted with the appropriate "Caution Radioactive Material" sign. In addition, the name and home phone number of the RSO will be posted on the door. All drums will be appropriately labeled with information about the drum's contents.

Liquid scintillation vial waste will be stored in 30 gallon drums and disposed of through a licensed waste disposal contractor.

Liquid radioactive wastes will either be stored for decay and then disposed of as non-radioactive liquid wastes, solidified and stored for removal and permanent disposal by a licensed disposal vendor, or disposed of via the sanitary sewage system. Liquid radioactive wastes disposed of via the sewage system must not exceed daily limits derived from Table 3 of Appendix B to 10 CFR 20. Based upon current water usage

of 600 gallons per day, and current plans of licensed material usage, the sink disposal limits will be as below:

Formula: $\frac{*\mu Ci}{ml} \times \frac{600\ gals}{day} \times \frac{3785.3\ ml}{gal} = \frac{\mu Ci}{day}$

*From 10 CFR 20, App. B, Table 3

Nuclide	App. B, Tbl 3 Derived Limit	Daily Limit	Derived/Daily Limit
^{3}H	22711 μCi/day	5000 μCi/day	0.22
^{14}C	681 μCi/day	200 μCi/day	0.29
^{32}P	204 μCi/day	20 μCi/day	0.10
^{35}S	2711 μCi/day	250 μCi/day	0.11
^{125}I	45 μCi/day	10 μCi/day	0.22
Sum of Fractions			0.94

The specific daily limits may be modified over the term of the license with changes in Sontra Medical research priorities. In no case, however, will the daily limit for an individual radionuclide exceed the 10 CFR 20, Appendix B, Table 3 limit, nor will the sum of the derived/daily limit fractions exceed one.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Michael Pishko	Scientist

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
University of Missouri, Columbia	B.S.	1986	Chemical Engineering.
University of Missouri, Columbia	M.S.	1987	Chemical Engineering.
University of Texas, Austin, TX	Ph.D.	1992	Chemical Engineering.

RESEARCH AND PROFESSIONAL EXPERIENCE

Postdoctoral Associate 1/95 to 3/96. Dept. of Chemical Engineering, Massachusetts Institute of Technology.
Research Engineer 1/93 to 12/94. E. Heller & Co. 2007 Kramer Ln., Ste. 103, Austin, TX 78758
Postdoctoral Fellow 6/92 to 12/92. Department of Chemical Engineering University of Texas.
Graduate Research Assistant 9/88 to 6/92. Department of Chemical Engineering University of Texas.

SELECTED PUBLICATIONS

Schmidtke, D. S., Pishko, C. P., Heller, A. "Redunant Sensors for In Vivo Glucose Measurements" *Anal. Chem.* in press.

Pishko, M. V. "Macromolecular Wiring of Oxidoreductases and Potential Interesting Applications" *Trends in Polymer Science* **1995**, *3*(**10**), 342.

Quinn, C. P.; Pishko, M. V.; Schmidtke, D. W.; Ishikawa, M.; Wagner, J. G.; Raskin, P.; Hubbell, J. A.; Heller, A. "Kinetics of Glucose Delivery to Subcutaneous Tissue in Rats: A Study Utilizing Amperometric Biosensors" *American Journal of Physiology* **1995**, *269*(Endocrinol. Metab. **32**), E155.

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Linke, B.; Kerner, W.; Kiwit, M.; Pishko, M.; Heller, A. "Amperometric Biosensor for *In Vivo* Glucose Sensing Based on Glucose Oxidase Immobilized in a Redox Hydrogel" *Biosensors and Bioelectronics* **1994**, *9*, 151.

Pishko, M.V. and Heller, A. " Enzyme Electrodes" McGraw-Hill Yearbook of Science and Technology, 1994.

Kerner, W.; Lindquist, S.-E.; Pishko, M. V.; Heller, A. "Amperometric Glucose Sensor Containing Glucose Oxidase, Cross-Linked with Redox Gels" *In Vivo* Chemical Sensors: Recent Developments Alcock, S. J. and Turner, A. P. F., ed. Cranfield Press; Bedford, UK; 1993.

Pishko, M. V.; Michael, A. C.; Heller, A. "Amperometric Glucose Microelectrodes Prepared through Immobilization of Glucose Oxidase in Redox Hydrogels" *Anal. Chem.* **1991**, *63* (20), 2268.

Pishko, M. V.; Katakis, I.; Lindquist, S.-E.; Heller, A.; Degani, Y. "Electrical Communication Between Graphite Electrodes and Glucose Oxidase/Redox Polymer Complexes" *Mol. Cryst. Liq. Cryst.* **1990**, *190*, 221.

Pishko, M. V.; Katakis, I.; Lindquist, S.-E.; Ye, L.; Gregg, B. A.; Heller, A. "Direct Electrical Communication between Graphite Electrodes and Surface Adsorbed Glucose Oxidase/Redox Polymer Complexes" *Angewandte Chemie, International Ed.* **1990**, *29* (1), 82.

Sontra Medical

Michael V. Pishko, Ph.D.
38 Rawson Rd.
Arlington, MA 02174
617-646-1912

- Trained at the University of Texas at Austin in the use of radiochemicals. Fall 1990.
- Iodinated proteins and used in in vitro experiments, used ^{3}H and ^{14}C labelled small molecules in both in vitro and in vivo experiments. Fall 1990-Summer 1992.
- Trained at Massachusetts Insititute of Technology in the use of radiochemicals. February 1995.
- Iodinated proteins and used in in vivo experiments, used ^{3}H and ^{14}C labelled small molecules in both in vitro and in vivo experiments. Fall Feb. 1995-Jan. 1996.

Sontra Medical, L.P.
767 C Concord Avenue
Cambridge, MA 02138-1044
617-497-0600 phone
617-497-8330 fax

Holly L. Veno
53 Hill Road #708
Belmont, MA 02178
(617) 484-7319

Education:

1996	Master of Science	Microbiology	University of New Hampshire
1992	Bachelor of Arts	Biology	Boston University

Professional Experience:

Research Associate at Sontra Medical, LP (April 1996-present)

MS project investigating the effect of surfactant on the phagocytosis of *Group B streptococci* by murine alveolar macrophages

Graduate Teaching Assistant for General Microbiology, Immunology, and Microbial Genetics Laboratories (Fall 1993-Spring 1996)

Supervising of undergraduate research projects (Spring 1994-Fall 1995)

Biology teacher for high school students (Summer 1994)

Undergraduate research and work in Stable Isotope Laboratory at Boston University (Spring 1989-August 1992)

Coordinating clinical research study on hypogonadism in men at Massachusetts General Hospital (May 1990-September 1990)

Skills:

Cell Culture
Immunoassays
Laboratory animal use; in vitro techniques
Electron, fluorescent, light microscopy
Monoclonal antibody production
Radioisotope usage
Sample preparation for ^{3}H and ^{18}O isotope analysis
Bacterial media preparation
Bacterial culturing
Bacterial identification
Western transferring
Electrophoresis (protein/DNA)

Computer Skills:

Macintosh and IBM
Proficiency in word processing, graphics, and statistical analysis
Entrez, Wordperfect, Word, Excel
Internet usage
Email

Presentations:

Departmental seminars on research (Spring 1996, 1995, Fall 1993)

Poster presentation at the Northeast Branch of the American Society of Microbiology meeting (March, 1996)

Manuscripts:

The effect of surfactant on the phagocytosis of *Group B streptococcus* by alveolar macrophages (in preparation)

Holly L. Veno continued

Professional Memberships:

American Society of Microbiology
American Association for the Advancement of Science

Awards:

Graduate Research Enhancement Award for Group B streptococcus research from the University of New Hampshire (1995-1996)

Graduate student mentor of Undergraduate Research Opportunity Program award winner (Spring 1996)

Tuition Scholarship University of New Hampshire (1992-1993)

References:

Dr. William Chesbro	University of New Hampshire	(603) 862-2250
Dr. Thomas Foxall	University of New Hampshire	(603) 862-2354
Robert Michener	Boston University	(617) 353-6980
Dr. Thomas Pistole	University of New Hampshire	(603) 862-2250

Holly L. Veno

-Trained at Boston University on the use and precautions of ^{3}H

-Trained at the University of New Hamshire on the use and precautions of ^{32}P and ^{35}S

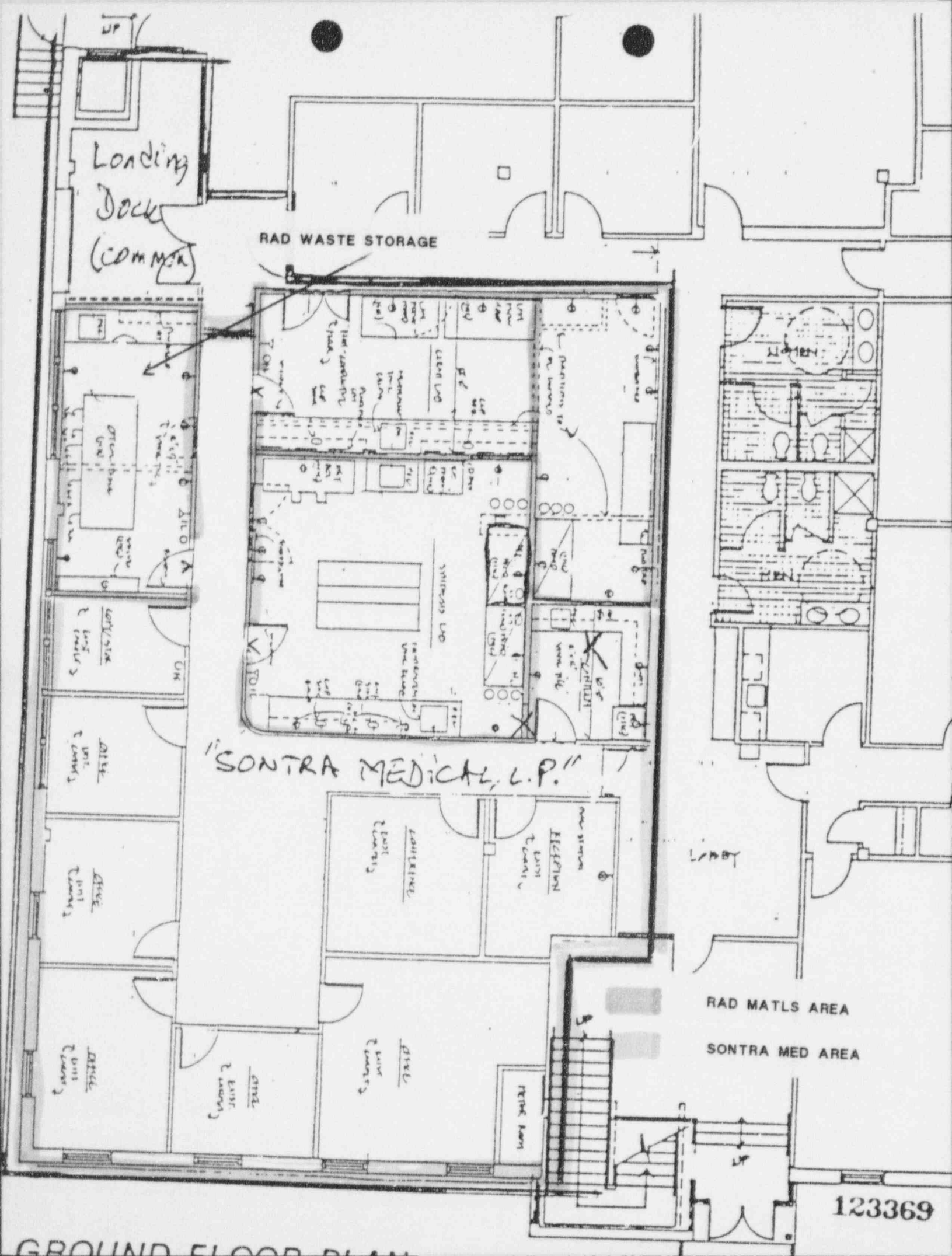
-Distilled water from blood samples of animals that had been labeled with ^{3}H and then analyze the isotope content of the samples

-Taught undergraduate students in a Microbial Genetics Laboratory on the technique of labeling and working with DNA that was labeled with ^{32}P

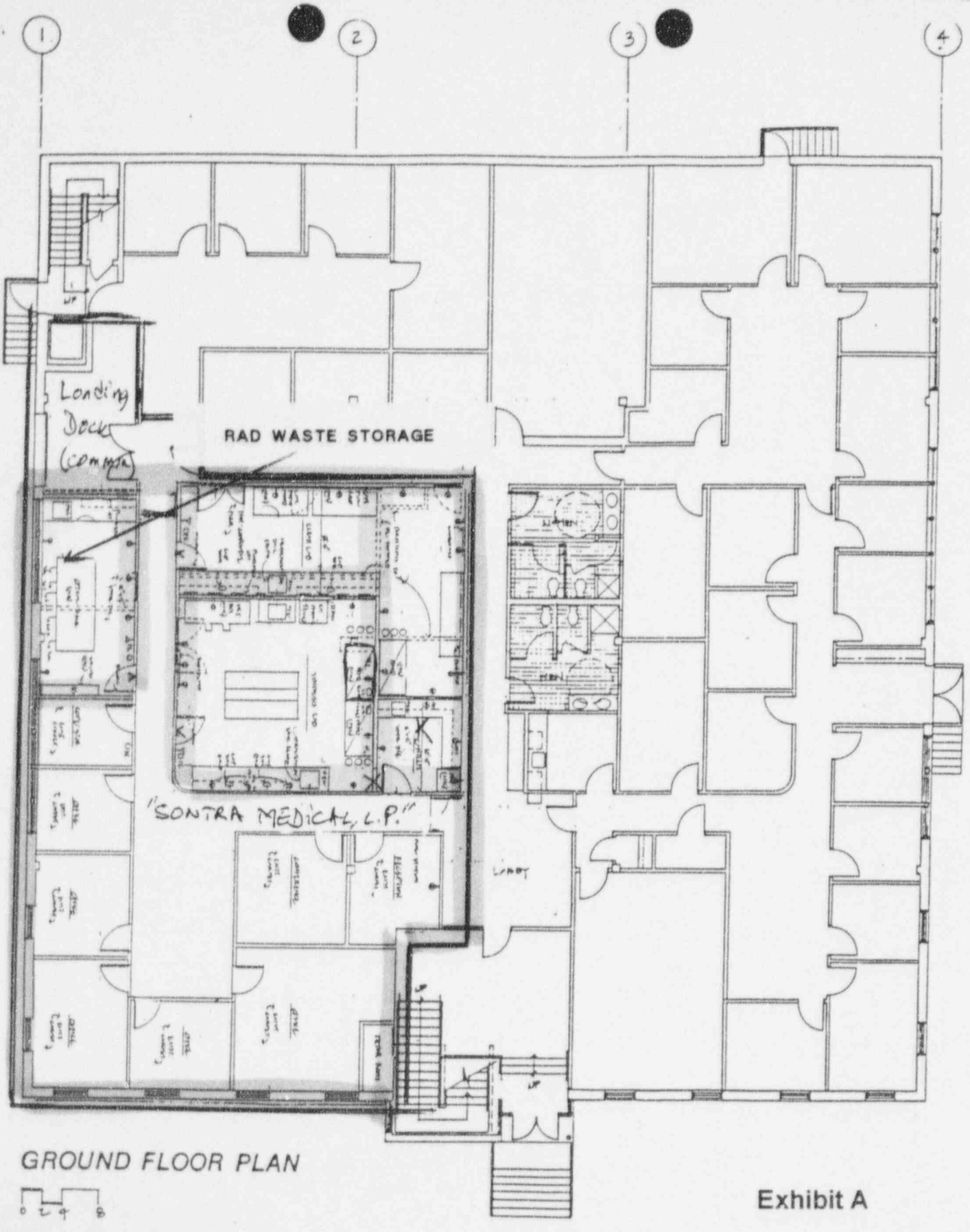
-Used ^{32}P to label isolated bacterial DNA and to run the radiolabeled DNA on an agarose gel for further detection

-Used ^{35}S to radiolabel bacteria that could then be used in assays to determine the adherence of the organism to different mammalian cells

Floor Plans



GROUND FLOOR PLAN



GROUND FLOOR PLAN

0 2 4 8

Exhibit A

Margolis+Fishman

Atwell Building

767c Concord Ave

SONTRA MED AREA

RAD MATLS AREA

OFFICIAL RECORD COPY ML 10

123369

SONTRA MEDICAL

RADIATION SAFETY GUIDE

21 June 1996

TABLE OF CONTENTS

INTRODUCTION

All uses of radioactive material at Sontra Medical are controlled by the radiation protection program.

NO WORK WITH SOURCES OF IONIZING RADIATION CAN BE INITIATED UNLESS AUTHORIZATION HAS BEEN OBTAINED FROM THE RADIATION SAFETY OFFICER.

All uses of ionizing radiation in Massachusetts are controlled and regulated by the U.S. Nuclear Regulatory Commission (NRC). Sontra Medical has established a radiation safety program to give the necessary assurances to the NRC as well as the company management that all potentially hazardous sources of radiation will be used safely. This guide describes the organization of the program and specifies the regulations, policies and procedures and practices which are to be followed when using radioactive materials.

It is Sontra Medical policy that the use of radioactive materials be kept to a minimum and that there be no unwarranted radiation exposure. Due regard must always be given to the safety and welfare of the radiation workers and the general population, as well as to the protection of Sontra Medical property and liability. The Sontra Medical operational policy places responsibility on the user and the persons who supervise use of radioactive materials. These supervisors can satisfy their responsibilities by adhering to this guide and by requesting assistance from the Radiation Safety Officer (RSO) when there are questions or suspected problems.

This guide is organized in the following manner:

Section 1 General description of the Sontra Medical Radiation Safety Program, Organization and Responsibilities

Section 2 Detailed Procedures and Practices

1. Description of the Sontra Medical Radiation Safety Program

There are three levels of authority in the radiation safety program:

The Radiation Safety Officer (RSO)

The RSO together with the management of Sontra Medical establishes the radiation safety policy such that:

1. Unwarranted radiation safety exposures of Sontra Medical employees and general public are avoided.

2. Compliance with all the federal and state regulations is assured.

3. Sontra Medical property and liability are protected.

Specifically, the RSO meets these responsibilities by routinely monitoring all uses of radioactive material to ensure that: (a) each use is by or under the supervision of a properly authorized supervisor, (b) that the appropriate personnel and environmental monitoring equipment is being used and (c) that radioactive material is properly secured against unauthorized removal when not in use.

The Authorized Supervisor (Scientists or Department Manager)

The supervisor has primary responsibility for the radiation safety associated with each source under his/her control. He must ascertain that each person under his supervision using these sources is properly trained and aware of the attendant hazards (see Training Requirements). He must also assure that use of the sources conform to all the safety conditions of this authorization and those of this guide.

The Supervised User

These individuals must use the sources of radiation only under the direction of a supervisor. They must follow those procedures and practices established by the supervisor. All users are required to attend a Radiation Safety Training Seminar before they begin work (see Training Requirements).

2. Radiation Regulations, Policies, Procedures and Practices

a. *Federal Regulations*

The Nuclear Regulatory Commission has established "Standards for Radiation Protection" 10 CFR 20 (see Appendix for a copy). These standards must be strictly adhered to during all uses of by-product material. The NRC also has adopted regulations which assure that workers will be advised of the sources of radiation being used, the hazards, the safety precautions in effect, etc. at the place of employment. These rights are present in "Notice of Instructions and Reports to Workers; Inspections", 10 CFR 19 (see Appendix for a copy).

b. *Sontra Medical Policies and Procedures*

The management of Sontra Medical recognizes both the NRC regulations and company policy of preventing unnecessary exposures to radiation as the basic criteria for establishing the radiation safety policies and procedures. The principle means by which the company assures the safe use of sources of radiation are:

1. To require that a person be authorized to use or supervise the use of radiation sources.

2. To require that the acquisition of radiation sources be approved by the RSO and that all receipts and transfers, including disposal of radioisotopes, be channeled through the RSO.

Specific procedures and practices have been established for most routine or recurrent situations to assure compliance to the regulations and company policy. For unusual situations, the RSO will interpret the existing regulations, policies and procedures to establish guidelines.

These are the established procedures and practices:

1. Authorization to Use Radioisotopes (Appendix 1)
2. Training of Workers (Appendix 2)
3. Use of Radioisotopes (Appendix 3)
4. Special Procedures (Appendix 4)
5. U.S. Nuclear Regulatory Commission Procedures (Appendix 5)

c. *Professional Standards*

The RSO also uses Health Physics consultants for specific advise and services. They are William E. Irwin and Judith M. Reilly, Assistant Radiation Protection Officers for the Massachusetts Institute of Technology. They have at their disposal the published data and recommendations of professionally recognized national and international committees and organizations concerned with health physics or radiation protection, examples of which are:

1. National Council on Radiation Protection (NCRP)
2. International Committee on Radiation Protection (ICRP)
3. International Atomic Energy Agency (IAEA)
4. Health Physics Society (HPS)

APPENDIX 1

Authorization to Use Sources of Radiation

An individual can use or possess radioactive materials only after (s)he has presented evidence of proper training and experience, read the Sontra Medical Radiation Safety Guide, and received training on the practical aspects of radiation protection from the RSO or his independent health physics consultant. Retraining and continuing education occur at least annually and technique specific training is provided by the supervisor. An authorization form must be submitted to the RSO and the RSO must approve the application.

A facsimile of the authorization use form is on the next page.

SONTRA MEDICAL
AUTHORIZATION TO USE RADIOACTIVE MATERIALS

Name _____ Date _____
(Print) Last First M.I.

Social Security Number _____ Birth Date _____

Job Title _____ Supervisor _____

Brief description of present work with radiation:

Principal radioactive materials to be used in your present work:

RADIONUCLIDE(S)	CHEMICAL OR PHYSICAL FORM	ESTIMATED ACTIVITY PER EXPERIMENT

Previous experience with radioactive material or radiation producing devices:

RADIONUCLIDES OR RADIATION DEVICE						
EST. TOTAL ACT. USED						
EMPLOYER(S) NAME & ADDRESS (Required for workers with dose during current year)					DATES FROM	TO

123369

Previous radiation protection training including Sontra Medical:

TRAINING DESCRIPTION	PROVIDER(S) NAME & ADDRESS (May be classroom or on-the-job-training)	DATES FROM	TO

I have received and read the Sontra Medical Radiation Safety Guide including Regulatory Guide 8.13, Instruction Concerning Prenatal Radiation Exposure. I have attended the Radiation Safety Training Program and was afforded the opportunity to ask questions addressing any concerns I have relating to potential occupational radiation doses. I agree to comply with Sontra Medical rules and regulations governing the safe use of radioactive materials.

_____ _____

Signature Date

TO BE COMPLETED BY THE RADIATION SAFETY OFFICER

Instruction Material Supplied: Radiation Safety Guide ____ Reg. Guides 8.13 and 8.29 ____

Film Badge: Yes ____ No ____ Body ____ Wrist ____ Finger ____

Spare Badge # _____ Reference # _____ Issue Date _____

Spare Badge # _____ Reference # _____ Issue Date _____

Spare Badge # _____ Reference # _____ Issue Date _____

Bioassay: Yes ____ No ____ Urinalysis ____ Radionuclides _____

In vivo Measurements: Whole Body _____ Thyroid _____

RSO Approval: _____ Date _____

Radiation Safety Officer

APPENDIX 2

TRAINING OF WORKERS

Individuals using radioisotopes under an NRC license have certain rights as prescribed in 10 CFR 19 "Notices, Instructions and Reports to Workers; Inspections" (see Appendix 5). In accordance with Part 19, a copy of the Sontra Medical license and a copy of the Notice is posted in radioisotope areas to advise persons in those areas where work is being done and to describe the documents and regulations pertinent to that work are included in this Appendix.

The RSO is in charge of radiation safety training at Sontra Medical. (S)he will either conduct personally the Radiation Safety Training Seminar or have it taught by an independent outside consultant.

Sontra Medical has designed its training program to assure that all persons working in or frequenting areas of radioisotope usage are aware of the attendant hazards. All persons using radioisotopes or frequenting areas where radioisotopes are used must attend the Training Seminar which covers the material shown on the following page. The RSO shall keep records of attendance at these orientations.

Training will also be provided for ancillary personnel who may frequent areas where radioactive material is stored or used. These housekeeping, maintenance, and security personnel will be trained in the appropriate precautions to take upon recognizing radiation warning signs and hazards.

Annual re-training seminars will be provided for ALL radiation workers. Radiation workers are defined as those individuals who have been authorized to use radioactive materials, as documented on Appendix 1, *Authorization to Use Radioactive Materials*.

Radiation Safety Training Program Outline

1. Regulatory Climate
   a. Agencies
   b. 10 CFR 19 and 10 CFR 20
2. Radiation Physics
   a. Definitions
   b. α, β, γ, and x Radiation
   c. Radionuclide Information
3. Radiological Units and Quantities
   a. Radiation
   b. Radioactivity
4. Radiation Dose Limits
   a. Background Radiation
   b. Dose Limits
5. Health Effects
   a. Somatic
   b. Genetic
   c. Teratogenic
6. ALARA
   a. Definition and Policy
   b. External Dose Reduction
   c. Internal Dose Reduction
   d. Contamination Control
   e. Radioactive Waste Reduction
7. Equations and Rules of Thumb
8. Emergency Procedures
9. Sontra Medical Radiation Safety Guide
10. NRC Information Notice 94-16
11. Glossary

CAUTION

Work with sources of radiation is being carried out in this area.

In accordance with the United States Nuclear Regulatory Commission Regulation 10 CFR 19.11, the following documents relating to work with radioactive materials are available to you from the Radiation Safety Officer.

1. 10 CFR 20

   Which describes the Nuclear Regulatory Commission Standards for Radiation Protection which must be adhered to in the use of sources of radiation.

2. 10 CFR 19

   Which describes the Nuclear Regulatory Commission's Regulations pertaining to notices, instructions, and reports to workers and inspections of radiation activities.

3. NRC License

   Which specify the special conditions under which radiation work must be carried out.

4. Sontra Medical Radiation Safety Guide

   Which specifies Sontra Medical radiation safety policies and procedures.

5. Any Notice of Violation

   NRC violations involving radiological working conditions, proposed imposition of civil penalty, or NRC order issued.

The Radiation Safety Officer is Michael Pishko, PhD. He may be reached at 497-8318

Custodial & Maintenance Staff Instructions

What to do About Radioactive Materials

1. Rooms which have the radiation symbol shown on doors or on equipment may contain radioactive materials. You must be careful when working in these rooms. You can sweep, mop, and wax the floors and remove the waste which is not labelled with the radiation symbol, just as in any other room.

2. Any container (box, bottle, carton, etc.) which has radioactive material in it will have the radiation symbol on it. You should not touch these containers. If the contents of these containers are spilled, DO NOT TOUCH THEM OR ATTEMPT TO CLEAN THEM UP. Tell your supervisor or the Radiation Safety Officer (RSO).

3. DO NOT empty any waste container which has the radiation symbol on it.

4. DO NOT empty any waste container which has waste material, such as boxes or bottles, with the radiation symbol in it. Tell your supervisor about it.

5. DO NOT eat, drink, smoke or apply cosmetics in any lab or in any room which has the radiation symbol on its door.

6. Before you work on or around a device or on a piece of equipment with a radiation symbol on it, contact the RSO so the device may be checked for safety.

7. If you think you may have gotten some radioactive material on your skin or clothing, call the RSO immediately. (S)he will assist with proper removal/decontamination.

8. In an emergency, or if you have any questions, ask your supervisor or the RSO for help.

APPENDIX 3

USE OF RADIOISOTOPES

The authorized supervisor is responsible for seeing that the users of radioisotopes under his supervision comply with all the governmental regulations, the specific conditions and limitations of his authorization, and the procedures and practices outlined in this Appendix. He ascertains that all persons who use radioisotopes under the coverage of his authorization are supervised, properly trained and experienced, aware of the attendant hazards, and observe the procedures of this guide.

Training and Experience

See Appendix 2 of this guide.

Receipt, Transfer and Disposal of Radioactive Material

All radioisotopes must be shipped to this address:

Sontra Medical
767C Concord Avenue
Cambridge, MA 02138
Attn: Radiation Safety Officer

Purchase orders for all radioactive materials must be signed by the RSO.

All radioisotopes received will be placed in a holding area. An individual specified by the RSO will check for contamination and record receipt. See Appendix 4 for procedures and forms.

All radioactive material must be disposed of through procedures approved by the RSO. Only those small amounts of liquid radioactive waste allowed by law may be disposed of down the drain of designated sinks. Liquid waste must be placed in a properly labelled plastic container. Solid waste must be placed in a properly labelled container lined with a plastic bag. Liquid scintillation vials must be kept separate. All radioactive waste will be packaged according to the waste vendor's specifications for removal to the disposal site.

Radiation Surveys

Authorized users conduct routine radiation and contamination surveys of their areas. The user must conduct these routine surveys as follows:

RADIATION SURVEYS ARE TO BE MADE BY THE USER AFTER EACH EXPERIMENTAL RUN OR AT THE END OF THE DAY RADIOISOTOPES ARE USED IN ORDER TO DETERMINE THE EXTENT OF RADIOACTIVE CONTAMINATION AND TO ASCERTAIN THAT ALL WASTE AND STOCK MATERIAL HAS BEEN **SECURED** OR PROPERLY DISPOSED OF.

In addition, the RSO or a designated independent consultant will conduct monthly surveys of all lab areas. All rooms where radioactive materials are used or stored are surveyed with an appropriately calibrated survey meter. Wipe tests are taken on surfaces including bench tops, hood ledges, sink areas, storage and waste disposal areas. Surveys will also check for proper labelling, signage, and adherence to rules and regulations by users.

When material is known to have been spilled or become airborne, wipe test surveys of the affected area must be made. Such tests can be made with filter paper or squares of any absorbent paper and the wipes counted with an appropriate counting instrument. The RSO must be called if a researcher has reason to believe his work has resulted in gross contamination or constitutes an emergency situation. (See Emergency Procedures below.)

Results from wipe tests are to verify that radioactive material use surfaces are less than 100 dpm/100 cm^2 for I-125, and 200 dpm/100 cm^2 for other radioisotopes. If activity levels are found to be higher than these limits, the area must be decontaminated and re-surveyed until survey results fall below these limits.

All radiation survey reports will be maintained by the RSO for inspection by the NRC. Records shall be retained for at least three years after the record is made.

Storage of Radioisotopes

Radioisotopes must be stored securely to permit access only to authorized users. Each area and room where radioisotopes are stored must be posted with a "Radioactive Material" sign. Radiation levels around storage areas must be measured. If radiation dose rates could exceed 5 millirem per hour in an occupiable area, the area must be posted with a radiation area sign. Proper signs can be obtained from the RSO.

Sontra Medical, or its licensed waste contractor, "decay-stores" waste from P-32 (14 day half-life), S-35 (87 day half-life), and I-125 (60 day half-life). Paper, plastic, and other lab trash expendables are securely stored in covered containers by isotope in a lockable storage room for 10 half lives. The waste is monitored with a survey meter and discarded in the trash only when no radiation above background is detectable.

Records

A receipt log book will be kept in the radiation holding area to record the receipt of radioactive materials. Log sheets for use and disposal will be kept and posted in appropriate areas. A survey log form will also be used to record the date and results of radiation and contamination surveys, even when the results are negative. Master radioactive material inventory sheets for each isotope will be kept by the RSO based on the information derived from the user logs.

Other records required by federal law are kept by the RSO.

Restriction of Radioisotopes Areas

Access to areas where radioisotopes are stored and used must be restricted to those persons cognizant of the associated hazards. Radioactive materials that are not in use by radiation workers must be secured from unauthorized access. Laboratory areas where radioactive materials are being used must either be occupied by a radiation worker maintaining control of those radioactive materials or locked to prevent unauthorized access.

Radioactive Waste

Radioactive waste must be disposed of through procedures approved by the RSO. No waste is to be washed down drains, incinerated, or otherwise disposed without prior clearance from the RSO. A copy of the detailed procedures for waste disposal is given in Appendix 4.

Emergency Procedures

A radiation emergency occurs when a set of circumstances results in hazardous radiation levels, hazardous concentrations of airborne radioisotopes, or gross contamination of property. Examples of radiation emergencies and actions to be taken are:

a. Personnel Contamination

1) Remove contaminated clothing.
2) Wash contaminated skin with mild soap and water. Do not use abrasives.
3) Call the RSO. After hours, refer to the emergency call list.

b. Spill of radioisotope where radioisotope does not become airborne

1) Wipe up with absorbent paper using a blotting motion so you do not spread contamination.
2) Dispose of contaminated materials in radioactive waste container.
3) Call the RSO. After hours, refer to the emergency call list.

c. Volatilization of liquid or dispersal of solid radioisotope outside a ventilated enclosure

1) If possible, keep contamination localized by closing doors and restricting access to area.
2) Leave the area.
3) Call the RSO. After hours, refer to the emergency call list.

d. Fire in radioisotope area.

1) Treat fire in normal manner.
2) Call the RSO. After hours, refer to the emergency call list.

EMERGENCY MEDICAL CARE TAKES PRECEDENCE IN LIFE THREATENING EMERGENCIES. ALWAYS USE COMMON SENSE IN HANDLING RADIATION EMERGENCIES AND CALL THE RSO AS SOON AS PRACTICAL. DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREAS.

SONTRA MEDICAL RADIATION SAFETY OFFICER:

Dr. Michael Pishko

DAYTIME PHONE: (617) 497-0600

WEEKEND AND EVENINGS: Refer to the emergency call list. A more detailed procedure can be found below.

Personnel Monitoring

The RSO determines the need for personnel dosimetry during the authorization evaluation or evaluation of amendment requests.

Sontra Medical requires all personnel using or routinely exposed to radioisotopes to wear film badges. Badges are supplied and analyzed monthly by Landauer, Inc., 2 Science Road, Glenwood, Illinois 60425-1586. Individuals using 1 mCi or more of P-32 or I-125 are also required to wear a finger ring or other extremity monitor. Monitoring reports are returned to the RSO, who reviews them along with an independent radiation safety consultant to assure that exposures are maintained within acceptable levels.

The authorized supervisor has the responsibility to assure that all persons who use radioisotopes or work in his(her) area wear appropriate radiation dosimeters when required.

Radioisotope Laboratory Design

The design and furnishings of a laboratory must be commensurate with the hazards presented by the radioisotope and its condition of use. In practical terms, some baseline requirements are that:

a. Bench tops or other surfaces on which radioisotopes will be used must either be made of or be covered with an impervious surface.

b. Floors must be covered with an impervious material; properly waxed, vinyl asbestos tiles are normally acceptable.

c. Walls must have a smooth, crack- and hole-free surface.

d. Proper room ventilation and adequate radioisotope storage must be provided.

Rules for Working with Radioactive Materials

The following pages outline the routine working procedures for handling radioactive materials at Sontra Medical.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES

Eating, drinking, smoking or using cosmetics is not permitted in the laboratory.

Wash hands after handling any radioactive material before going about other work.

Never pipette anything, even water, by mouth.

Always wear safety glasses in the laboratory.

Always use rubber or plastic gloves when handling radioisotopes. Protective gloves must be removed before leaving the laboratory to avoid contaminating doorknobs and telephones. Lab coats must be worn in the lab and left in the laboratory.

Notify the Radiation Safety Officer of all spills .

Label radioactive material with your name, date, isotope and quantity of isotope.

Before leaving the laboratory, clean up and monitor your work area and yourself.

Liquid radioactive materials must be stored in plastic containers or in metal containers if the material is incompatible with plastic. The quantity of isotope, the isotope name, date, and the user's name must be recorded in a log kept with the container. A log is also kept of all liquids disposed of at designated sinks.

Solid radioactive waste must be placed in plastic-lined boxes or containers. When filled, the contents are transferred to a drum in the waste storage room.

Work over bench paper or other absorbent material except where H-3 and C-14 are used. Where long-lived radioactive materials are used, washable trays should be used in place of absorbent materials to minimize long-lived solid waste. Keep and transport radioactive materials doubly contained.

Materials which could become airborne must be stored and used in a hood. Hood ventilation shall be left "ON" at all times.

Never keep or store beverages or food in radioisotope labs, or in refrigerators or freezers with radioisotopes.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

EMERGENCY PROCEDURES

EXTREME HAZARDS: Hazards such as high radiation levels or the possibility of airborne contamination from dry or volatile radioactive materials.

Evacuate Evacuate the laboratory immediately; close the door and lock it.

Call RSO Call the RSO immediately. If you have to leave the area to do so, remove your shoes if you suspect contamination and do not touch anything unnecessarily.

OTHER HAZARDS: Hazards such as spills or suspected spills of radioactive material where the material does not become airborne.

Keep Calm Keep calm, use common sense, protect people, do not spread contamination (always assume you are contaminated until a survey proves otherwise).

Confine Localize the spill. Right tipped container; drop absorbent material on the spill. Damp down a dry spill. Do not track contamination about the laboratory. Call, do not go for help, if possible! Close door, and where possible adjust the ventilation to prevent spread of airborne material. Check shoes before leaving the area of a cleaned up spill.

Protect Personnel Remove contaminated clothing and wash contaminated parts of the body with detergent. Be especially thorough in flushing out wounds. Warn other workers.

Decontaminate If thorough washing with detergent does not remove contamination from body, consult the RSO. You will be expected to perform the major work of decontamination of the area of your spill. The RSO will survey for contamination and advise on procedures and assist as necessary. All suspected contaminated persons and areas must be monitored after decontamination and before work is resumed.

EMERGENCY MEDICAL CARE TAKES PRECEDENCE IN LIFE THREATENING EMERGENCIES.

IN ALL EMERGENCIES, EXCEPT VERY MINOR SPILLS OF RADIOACTIVE MATERIALS, THE RSO MUST BE CALLED AS SOON AS POSSIBLE.

DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREAS.

APPENDIX 4

SPECIAL PROCEDURES

Monthly Laboratory Survey Procedure

1. Laboratory contamination surveys shall be done on a monthly basis, either by the RSO or his or her designate or an independent consultant.

   (Surveys must also be done by the researcher using radioactive materials immediately after the completion of an experimental procedure.)

2. A survey data notebook must be kept, containing layouts of the laboratories indicating the points at which the wipes were made and data tables containing the results of the counting of the wipes.

3. Wipes are made using filter paper. Approximately 100 square centimeters of surface should be wiped.

4. Penetrating beta radiation, e.g. P-32 can be monitored with the G-M survey instrument.

5. For low levels of I-125, a NaI scintillation detector is required for contamination monitoring.

6. Tritium (H-3) cannot be measured with portable instruments available. Areas surveyed for tritium contamination must be wipe tested. After surfaces have been wiped, the wipes must be counted by liquid scintillation counting using the appropriate LSC protocol.

Radioactive Material Receipt and Opening Procedure

1. Radioactive material packages are separated from others upon receipt. If a package contains ≥ 1 mCi of P-32 or I-125, extremity dosimetry must be worn by the person performing radioisotope receipt and delivery.

2. If the shipment appears damaged, ask the carrier to remain and record any signs of damage to the package or its contents.

3. A radiation and contamination survey must be made within 3 hours of radioactive material receipt if received during normal working hours, or not later than 3 hours from the beginning of the next working day for receipt after working hours.

4. Radioactive material receipt and survey is documented on the *Radioisotope Receipt and Delivery* form. Radiation levels are measured with a G-M survey meter, and tritium wipe tests are counted with a liquid scintillation counter.

5. Wipe approximately 300 cm^2 (about 7" X 7") of the package external surface, count the wipes for contamination, and record the results. The package must be ≤ 10^{-5} $\mu Ci/cm^2$.

6. Measure the highest radiation levels at the package surface and at 1 meter from the package surface, and record the results. Acceptable radiation levels are listed on the receiving form.

7. Packages of radioactive material are to be opened only in the designated radioisotope laboratories unless there is evidence of physical damage. If there is evidence of damage, the inner contents must be surveyed with the survey results recorded, and the RSO notified.

8. If all wipe tests are ≤ 10^{-5} $\mu Ci/cm^2$ and the radiation levels are acceptable, the radioisotope may be delivered, otherwise contact the RSO to check 10 CFR 20.1906 for appropriate organizational response.

9. Do not leave radioactive materials unattended; deliver immediately to the user for proper storage. If the user cannot be found, contact the user's lab supervisor for proper disposition.

10. After verifying package and packing material radiation levels are at background levels and all wipe tests are less than 10^{-5} $\mu Ci/cm^2$, the package and packing materials may be discarded in regular trash; otherwise the package and/or packing materials must be discarded with solid radioactive waste.

Sontra Medical

Radioisotope Receipt and Delivery

Purchase Order #_____ Date of Receipt_____

Isotope Ordered_____ Isotope Received_____

Activity Ordered_____ Activity Received_____

External Package Contamination: _____ $\mu Ci/cm^2$

Radiation Level at Surface: _____ mR/hr

Radiation Level at 1 Meter: _____ mR/hr
(Transport Index)

Packages above the following limits are held for notification to vendor, shipper, and NRC. Contact the RSO immediately.

Contamination: $\leq 10^{-5}$ $\mu Ci/cm^2$
Radiation levels:

White I Label	0.5 mR/hr @ surface	background @ 1 meter
Yellow II Label	50 mR/hr @ surface	1 mR/hr @ 1 meter
Yellow III Label	200 mR/hr @ surface	10 mR/hr @ 1 meter

Damaged Package Survey

Description of Damage:

Contamination level: _____ $\mu Ci/cm^2$
Radiation level: _____ mr/hr

Date and Time of Delivery to User _____

User Signature _____

Guidelines for Iodinations

Iodine in the unbound state volatilizes readily and is efficiently taken into the body by inhalation or absorption through the skin. Approximately 30% of the activity taken in remains in the thyroid. I-125 has an effective half-life of about 42 days. Thus, the predominant concerns with handling unbound iodine are preventing inhalation through the use of sufficient ventilation, and preventing absorption through the skin using protective clothing. Equally important, Sontra Medical must measure radioiodine activity released to the environment. All radioiodine work therefore must be performed under strict controls.

1. Always work in a well-ventilated hood. A lucite inner hood (mini-hood) with a charcoal filter on its discharge may be used. Monitoring of the breathing zone air and the hood air exhaust will be performed. Charcoal impregnated filters or activated charcoal canisters are used for air sample collection of iodines.

2. Written procedures for iodinations are approved and maintained by the Radiation Safety Officer. Procedures must be designed to minimize the opening of any vials through the use of syringe injection of material through septum-topped vials. All containers of the radioactive material must be sealed in some manner, e.g. rubber stoppers, plastic wrap or parafilm.

3. Conduct a dry-run of the procedure to minimize the chance of error when activity is used.

4. A baseline thyroid measurement must be performed for anyone participating in the iodination.

5. Wear a whole body personnel radiation dosimeter. Wear an extremity monitoring finger ring when working with $\geq$ 1 mCi.

6. Wear the proper protective clothing, safety glasses and two layers of protective gloves. Iodine diffuses rapidly through vinyl and rubber so replace the outer protective gloves immediately when they become contaminated. Keep the inner pair of gloves free of contamination.

7. Have a properly calibrated survey meter equipped with a NaI detector on and readily available for quick contamination checks. Be careful not to contaminate the instrument itself.

8. Avoid handling the vials directly. Use remote handling devices such as tongs or forceps.

9. To decontaminate equipment or surfaces, use a solution which efficiently removes the contamination without releasing iodine to the atmosphere.

10. All waste must be sealed in double layers of plastic and disposed of immediately.

11. The activity concentration of the exhaust must be monitored to assure compliance with NRC regulations concerning release of radio-iodine to the environment.

12. Clean and check all the working surfaces and equipment for contamination immediately after the procedure is finished. Take contamination wipes and count them with your samples.

13. Obtain a thyroid iodine burden measurement within 72 hours of the iodination.

14. IT CANNOT BE EMPHASIZED TOO STRONGLY THAT NEAT, CAREFUL WORK HABITS WILL MINIMIZE BOTH CONTAMINATION PROBLEMS AND UNNECESSARY EXPOSURE TO PERSONNEL.

Handling Procedures for Millicurie Quantities of Phosphorus-32

Phosphorus 32 emits a distribution of energetic beta particles, up to a maximum energy of 1.7 MeV, which can travel as far as 5 meters in air. The absorbed dose rate close to containers of millicurie quantities of P-32 is on the order rads/min. A significant fraction of P-32 entering the body deposits in the bone structure. The annual limit of intake is 600 microcuries.

The following procedures should offer a guide to using sources of P-32 in excess of one millicurie.

1. Prepare a written set of procedures for RSO for approval prior to the run.

2. Avoid handling the vial directly. Use remote handling tools, such as tongs or special holders when handling the source containers.

3. Use low density shielding (e.g. a minimum of 0.25 in. of plexiglass) to absorb the beta particles without generating significant amounts of X-rays by the interactive process called Bremsstrahlung. High density or high atomic number materials must not be used close to the source because the Bremsstrahlung process is much more efficient for these materials. However, a small amount of lead on the outside of a plastic shield will absorb the Bremsstrahlung X-rays efficiently.

4. Always wear safety glasses to protect eyes from splashes and unnecessary radiation when working with radioactive materials.

5. Wear two sets of gloves; strip the outer pair off and replace if they become contaminated. Keep the inner pair clean at all times.

6. Have immediately available a properly operating G-M survey meter for use in detecting contamination and radiation fields.

7. Wear personal dosimeter and finger dosimeters. The finger dosimeters are important because they will monitor the dose given to the fingers which the body dosimeter will not see. Wear the finger dosimeter on the hand likely to receive the greatest dose.

8. Have your supervisor or the RSO observe during your first procedure.

9. After each procedure, survey the area to check for contamination.

Radioactive Waste Handling Procedures

SPECIFIC GUIDELINES FOR BAGGING DRY WASTE

Persons handling radioactive waste must wear a film badge, disposable gloves, and a lab coat. Persons must avoid working over the uncovered waste since an uncovered direct path from a concentrated radioactive surface is not attenuated.

Make sure that dry waste is bagged in heavy duty polyethylene bags and that the bags are tightly sealed. Log the waste disposal amounts on the log sheet attached to the lid of the drum.

Procedure

1. Whenever possible, radioactive material will be stored for radioactive decay and subsequent disposal as non-radioactive waste. All such material will be held for a minimum of 10 half-lives and will be surveyed completely prior to disposal. Survey results must be background before any material is disposed of as normal trash and all references to radioactive material will be removed or obliterated. A record of the radionuclide, amount stored, date of storage, date surveyed, survey results and date disposed must be kept for all decay in storage waste along with a record of the surveyor.

2. All solid material contaminated with radioactive material having a half-life less than 65 days and S-35 (half-life of 88 days) will be stored "in house" or transferred to a licensed waste disposal facility for radioactive decay and subsequent disposal as non-radioactive waste. Contaminated solids will be put in the waste containers provided for each laboratory. A record of the isotope and the amount being disposed will be maintained. When these containers are full, the waste will be transferred to 30 or 55 gallon drums and stored in the locked storage facility, or transferred to a licensed disposal facility, for decay. No liquids are to be put in the solid waste containers. The drums are to be labeled with the contents, the date the drum was full, and the date the waste has decayed through 10 half-lives and is ready for survey.

3. All other solids contaminated with radioactive material with a half-life greater than 65 days or with S-35, e.g. H-3 and C-14, must be segregated from the waste in #2 above and stored in a 30 or 55 gallon steel drum. These long half-lived materials will be disposed of as low level radioactive waste through a licensed disposal company.

4. Liquid radioactive waste will be disposed of via the sanitary sewage system in accordance with 10 CFR 20.2003 and the applicable concentrations in Appendix B Table II. Any liquids which cannot meet these requirements will be absorbed and disposed of as solid low level radioactive waste.

Most aqueous waste can be disposed of down a properly labeled and designated lab sink. Amounts disposed must be recorded at the sink. Sontra Medical will specify allowable disposal limits for each licensed radionuclide that ensure that no individual nuclide is disposed of in excess of the 10 CFR 20, Appendix B sewage disposal limit for that radionuclide. At the same time, Sontra Medical will assure that the summed ratios of the radionuclide disposal activities and their 10 CFR 20 disposal limits is less than one. If the aqueous waste is greater than the allowable limits, it must be stored in separate containers (segregated by isotope) and stored for proper disposal.

NOTE: Use of absorbent for liquid ^{3}H or ^{14}C generates solid waste which is very bulky and must be disposed of at great cost, so avoid this method of disposal whenever possible.

SINK DISPOSAL IS REGULATED AND INSPECTED BY THE NRC. VIOLATION OF THESE DISPOSAL PROCEDURES COULD RESULT IN THE LOSS OF SINK DISPOSAL RIGHTS AND RESTRICTIONS ON FUTURE COMPANY USE OF ISOTOPES!

APPENDIX 5

ALARA PROGRAM

Sontra Medical

1. Management Commitment

We, the management of Sontra Medical, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization is supervised by the Radiation Safety Officer (RSO).

We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with outside radiation protection professionals.

Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

In addition to maintaining doses to individuals as low as reasonably achievable, the sum of doses received by all exposed individuals will also be maintained at a lower practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Officer

Review of Proposed Users and Uses

The RSO will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

When considering a new use of byproduct material, the RSO will review the efforts of the applicant to maintain exposure ALARA.

The RSO will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

Review of ALARA Program

The RSO will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

The RSO, or an outside consultant, will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, supervisors, and authorized users as well as those of management.

Annual and Quarterly Review

Annual review of the radiation safety program. The RSO, or an outside consultant, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of supervisors and authorized users to determine that their doses are ALARA in accordance with the provisions of Section V of this program.

Quarterly review of records of radiation surveys. The RSO, or an outside consultant, will review radiation surveys in uncontrolled and controlled areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.

Education Responsibilities for ALARA Program

The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

The RSO will ensure that supervisors, authorized users, and ancillary personnel

who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

The RSO will be in close contact with all workers in order to develop ALARA procedures for working with radioactive materials.

The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes.

When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

Authorized Users

The authorized user will consult with the RSO during the planning stage before using radioactive materials for new uses.

The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

Individuals Who Receive Occupational Radiation Doses

Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

Workers will be instructed in resources available if they feel that ALARA is

not being promoted on the job.

Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), the results of personnel monitoring not less than once in any calendar quarter as required by 10 CFR Part 20.

The following actions will be taken at the investigational levels as stated in Table 1:

Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigation Level I.

Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I.

If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the RSO files.

Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action.

A report of the investigation, any actions taken, and a copy of the individual's form NRC-5 or its equivalent will be recorded in

the RSO files and the individual's personal file.

Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group of workers' doses exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices.

Justification for new investigational levels will be documented.

Table 1
Investigational Levels In Millirem Per Calendar Quarter

	Level I	Level II
The total effective dose equivalent	125	375
The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye	1250	3750
The eye dose equivalent	375	1125
A shallow dose equivalent to the skin or any extremity	1250	3750

Definitions:

Dose equivalent means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert.

Total effective dose equivalent means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Committed effective dose equivalent is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues.

Committed dose equivalent means the dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50 year period following the intake.

Deep dose equivalent, which applies to external whole body exposure, is the dose equivalent at a tissue depth of 1 cm.

Eye dose equivalent applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm.

Extremity means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

APPENDIX 6

POLICY REGARDING PREGNANT RADIATION WORKERS WHO ARE POTENTIALLY EXPOSED TO IONIZING RADIATION

Introduction:

Current regulations of the US Nuclear Regulatory Commission (NRC) and the Massachusetts Department of Public Health governing occupational doses to ionizing radiation require that the radiation dose to the fetus of occupationally exposed declared pregnant women be held to 500 millirem (5 mSv) or less during the pregnancy. The National Council on Radiation Protection (NCRP) has recently recommended that this dose be controlled such that no more than 50 millirem (0.5 mSv) be delivered to the fetus in any one month.

For the majority of radiation workers at Sontra Medical, the occupational doses received through normal work practices fall well below these more restrictive limits for declared pregnant workers. Occupational radiation doses are measured by film badges with a monthly exchange frequency. Hence, it is anticipated that there should generally be little difficulty in complying with the applicable limits. All radiation workers, women of child-bearing age especially, are encouraged to carefully monitor their film badge readings and become familiar with their potential sources of dose and practical means for keeping their doses as low as reasonably achievable. The Radiation Safety Officer carefully monitors film badge dose results monthly as part of the Institute's ALARA program.

It is the responsibility of the Radiation Safety Officer (RSO) to formulate, implement, and review radiation protection policies such that they are compliant with federal and state regulations. The purpose of this memo is to set forth the Sontra Medical policy with respect to the occupational duties of pregnant employees who may be exposed to ionizing radiation.

Sontra Medical Policy:

The following are the formal policies for the radiation worker who informs her supervisor that she believes she is pregnant.

1. It is the responsibility of the pregnant radiation worker to decide when or whether she will formally declare her condition to her employer. Formal declaration of pregnancy by the woman is initiated when the Radiation Safety Officer receives a completed copy of the "**Declaration of Pregnancy for Radiation Workers**" form. This form must be completed by both the pregnant woman and her supervisor. A copy of this form will be maintained with the workers radiation registration form. Undeclared pregnant radiation workers are protected under NRC regulations for all occupationally exposed workers.

2. In keeping with state and federal recommendations to hold embryo/fetus doses ALARA (As Low As Reasonably Achievable), if the pregnant employee is currently assigned to duties whereby her potential dose is significantly above the 500 mrem limit for the pregnant worker, she may request to be reassigned to duties involving lower potential for dose for the duration of her pregnancy if such temporary reassignment is deemed administratively practical.

3. Pregnant radiation workers are encouraged to be particularly diligent in avoiding unnecessary dose during their regular work assignment, by minimizing their time of dose, maximizing their distance from the radiation source, and by taking maximum advantage of available protective equipment such as bench shields and other appropriate shielding devices (stock vial shields, waste container shields, etc.).

4. After reassignment, if practical, or while implementing the above procedures to minimize potential radiation dose to the fetus, the pregnant employee will be expected to perform all duties assigned.

5. A copy of this policy will be given to all women radiation workers at the time of their employment or radiation safety training. A second copy will be provided if and when a pregnant employee informs her supervisor of her pregnancy. The pregnant employee is encouraged to discuss the potential for fetal dose and methods for controlling the same with her supervisor and the Sontra Medical Radiation Safety Officer in her consideration of this issue.

The above policy is believed to be conservative in many respects. Typically, radiation workers at Sontra Medical do not receive significant radiation doses due to their work with radioactive materials. However, pregnant radiation workers will be carefully monitored to assure that their doses are kept as low as reasonably achievable.

All Sontra Medical radiation workers are required to receive radiation protection training by the RSO, or an outside consultant, prior to the start of work with radioactive materials. Regulatory Guide 8.13, "Instructions Concerning Prenatal Radiation Exposure", is distributed to all workers and the contents reviewed during the training seminar. This policy will also be distributed during training seminars and discussed with the workers.

SONTRA MEDICAL RADIATION WORKER DECLARATION OF PREGNANCY

I. DECLARATION OF PREGNANCY

Name of Individual	
Social Security Number	
Date of Conception (Mo/Yr)	
By providing this information to my immediate supervisor, in writing, I am declaring myself to be pregnant as of the date shown above. Under the provisions of 10 CFR Part 20.1208 I understand that my dose will not be allowed to exceed 500 mrem (5 mSv) during my pregnancy, from occupational dose to radiation. I understand that this limit includes dose I have already received. If my estimated dose since the above date of conception has already exceeded 500 mrem (5 mSv), I understand that I will be limited to no more than 50 mrem (0.5 mSv) for the remainder of my pregnancy. If I should find out that I am not pregnant, or if my pregnancy is terminated, I will inform my supervisor as soon as practical.	
Signature of Individual	
Date Signed	

II. DESCRIPTION OF CURRENT WORK WITH IONIZING RADIATION

Note principal radioactive materials used & include maximum amount used/use per experiment:

III. RECEIPT OF DECLARATION OF PREGNANCY

Name of Supervisor	
Name of RSO	
I have received notification from the above named woman that she is pregnant. I have explained to her the potential risks from dose to radiation as provided in Regulatory Guide 8.13, Revision 3. I have evaluated her prior dose and established appropriate limits to control the dose to the developing embryo/fetus in accordance with limits in 10 CFR part 20.1208. I have explained to her options for reducing her dose to as low as reasonably achievable (ALARA).	
Signature of Supervisor	Signature of RSO
Date Signed	Date Signed

APPENDIX 7

NUCLEAR REGULATORY COMMISSION REGULATIONS AND GUIDES

10 CFR 20

10 CFR 19

Regulatory Guide 8.10

Regulatory Guide 8.13

Regulatory Guide 8.29

Gamma Scintillation

Model 44-3

Model 44-17

Common Specifications

INDICATED USE: ^{125}I, and X-Ray survey
RECOMMENDED ENERGY RANGE: Approximately 10 - 60 keV
ENERGY RESPONSE: Energy dependant
COMPATIBLE INSTRUMENTS: General purpose survey meters, ratemeters, and scalers
OPERATING VOLTAGE: Typically 800 - 1200 volts

	44-3	44-17
SCINTILLATOR	1"(2.5cm) diameter 1mm T NaI(Tl) crystal	2"(5.1cm) diameter 2mm T NaI(Tl) crystal
ENTRY WINDOW	15 mg/cm² *	43 mg/cm²
WINDOW AREA	2 cm² active and open	17.8 cm² active and open
BACKGROUND	40 cpm/μR/hr	160 cpm/μR/hr
EFFICIENCY (4pi geometry)	19% - ^{125}I	20% - ^{125}I
SENSITIVITY	675 cpm/μR/hr (^{125}I)	N/A
TUBE	1.5(3.8cm) diameter magnetically shielded photomultiplier	2"(5.1cm) diameter magnetically shielded photomultiplier
DYNODE STRING RESISTANCE	100 megohm	60 megohm
SIZE	2"(5.1cm) diameter 7"(17.8cm)L	2.6"(6.7cm) diameter 9"(22.9cm)L
WEIGHT	1 lbs (0.5kg)	1.5 lb (0.7kg)

***Model 44-3 is also available with a 7,8 mg/cm² window for energies as low as 5 keV**

Alpha Beta-Gamma G-M

Model 44-7

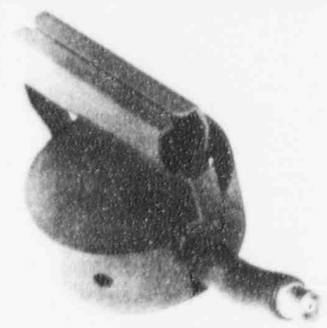
END WINDOW G-M DETECTOR

Model 44-9

PANCAKE G-M DETECTOR

Model 44-40

SHIELDED PANCAKE G-M DETECTOR



Common Specifications

INDICATED USE: Alpha, beta-gamma survey; sample counting
WINDOW: 1.7 ± 0.3 mg/cm² mica
ENERGY RESPONSE: Energy dependant
COMPATIBLE INSTRUMENTS: General purpose survey meters, ratemeters, and scalers
OPERATING VOLTAGE: 900 volts

Model 44-88

PANCAKE G-M DETECTOR

	44-7	44-9	44-40	44-88
DETECTOR	End window halogen quenched G-M	Pancake type halogen quenched G-M		
WINDOW AREA	6 cm² active 5 cm² open	15 cm² active 12 cm² open		
EFFICIENCY (4pi geometry)	2%-^{14}C; 10%-^{90}S/^{90}Y; 7%-^{239}Pu	5%-^{14}C; 22%-^{90}S/^{90}Y; 19%-^{99}Tc; 32%-^{32}P; 15%-^{239}Pu		
SENSITIVITY	Typically 2100 cpm/mR/hr	Typically 3300 cpm/mR/hr		
DEAD TIME	Typically 200 µs	Typically 80 µs		
CONSTRUCTION	Anodized aluminum housing	Aluminum housing	Lead housing*	Aluminum housing
SIZE	1.8"(4.6cm) diameter 5.8"(14.7cm)L	1.8"(4.6cm)H 2.7"(6.9cm)W 10.7"(27.2cm)L	4.5"(11.4cm)H 4"(10.2cm)W 6.5"(16.5cm)L	2.3"(5.7cm) diameter 2.8"(7cm)L
WEIGHT	1 lb (0.5kg)	1 lb (0.5kg)	5.5 lbs (2.5kg)	0.5 lbs (0.2kg)

*** Model 44-40-2 with aluminum cased lead shield is also available**

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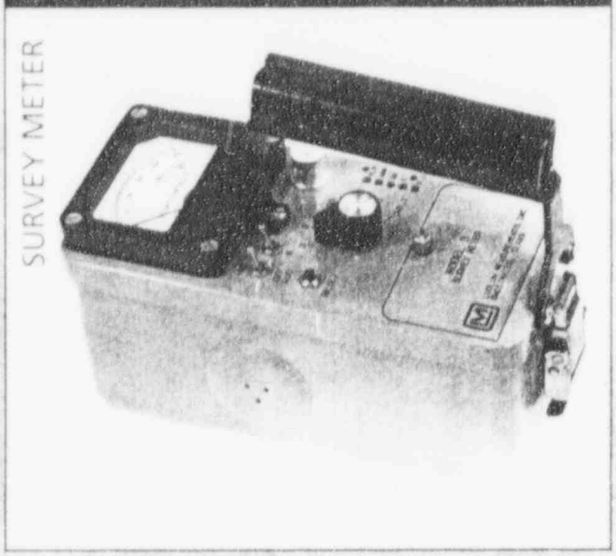
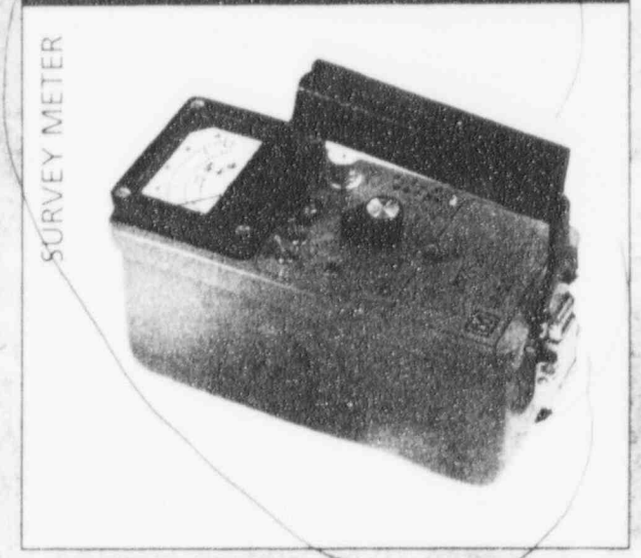
General Purpose Survey Meters

Model 3



Note: The Model 3 is also available with an alarm circuit. (Model 3A)

Model 14C



0-2,000 mR/hr Total Range

Common Specifications

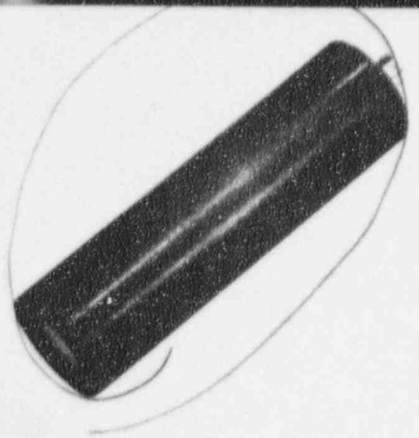
COMPATIBLE DETECTORS: G-M, scintillation
THRESHOLD: 30 mV ± 10 mV
SIZE: 6.5" (16.5 cm)H X 3.5" (8.9 cm)W X 8.5" (21.6 cm)L
WEIGHT: 3.5 lbs (1.6 kg) including batteries

	MODEL 3	MODEL 14C
METER DIAL (others available)	0 - 2 mR/hr, or 0 - 5k cpm, BAT TEST	0 - 2 mR/hr and cpm, BAT TEST
MULTIPLIERS	x0.1, X1, X10, X100	x0.1, X1, X10, X100, X1000
INTERNAL DETECTOR	N/A	Energy compensated G-M (used with X1000 range only)
ENERGY RESPONSE	Dependant on detector used	Within ± 15% of true value between 60 keV - 3 MeV (internal detector only)
HIGH VOLTAGE	Ajustable from 200-1500 volts	900 V

Gamma Scintillation

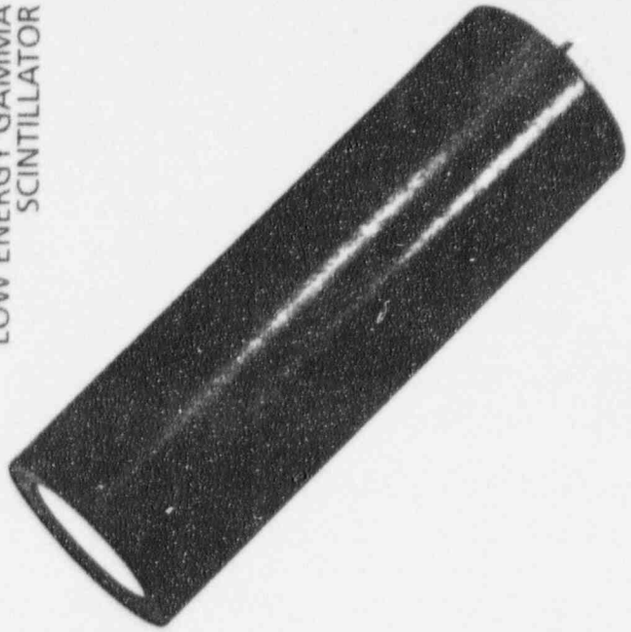
Model 44-3

LOW ENERGY GAMMA SCINTILLATOR



Model 44-17

LOW ENERGY GAMMA SCINTILLATOR



Common Specifications

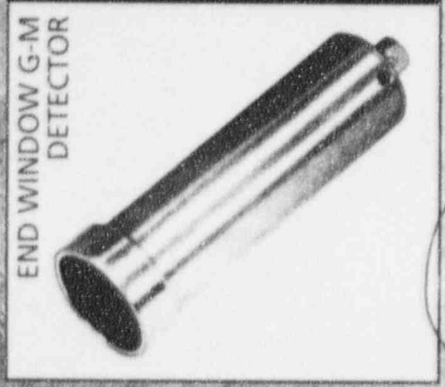
INDICATED USE: ^{125}I, and X-Ray survey
RECOMMENDED ENERGY RANGE: Approximately 10 - 60 keV
ENERGY RESPONSE: Energy dependant
COMPATIBLE INSTRUMENTS: General purpose survey meters, ratemeters, and scalers
OPERATING VOLTAGE: Typically 500 - 1200 volts

	44-3	44-17
SCINTILLATOR	1"(2.5cm) diameter 1mm T NaI(Tl) crystal	2"(5.1cm) diameter 2mm T NaI(Tl) crystal
ENTRY WINDOW	15 mg/cm² *	43 mg/cm²
WINDOW AREA	2 cm² active and open	17.8 cm² active and open
BACKGROUND	40 cpm/μR/hr	160 cpm/μR/hr
EFFICIENCY (4pi geometry)	19% - ^{125}I	20%-^{125}I
SENSITIVITY	675 cpm/μR/hr (^{125}I)	N/A
TUBE	1.5(3.8cm) diameter magnetically shielded photomultiplier	2"(5.1cm) diameter magnetically shielded photomultiplier
DYNODE STRING RESISTANCE	100 megohm	60 megohm
SIZE	2"(5.1cm) diameter 7"(17.8cm)L	2.6"(6.7cm) diameter 9"(22.9cm)L
WEIGHT	1 lbs (0.5kg)	1.5 lb (0.7kg)

***Model 44-3 is also available with a 7.8 mg/cm² window for energies as low as 5 keV**

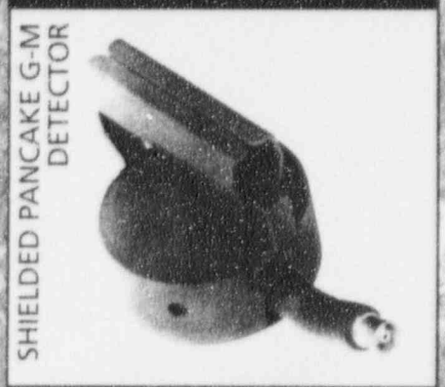
Alpha Beta-Gamma G-M

Model 44-7



Model 44-9

Model 44-40



Common Specifications

INDICATED USE: Alpha, beta-gamma survey; sample counting
WINDOW: 1.7 ± 0.3 mg/cm² mica
ENERGY RESPONSE: Energy dependant
COMPATIBLE INSTRUMENTS: General purpose survey meters, ratemeters, and scalers
OPERATING VOLTAGE: 900 volts

Model 44-88

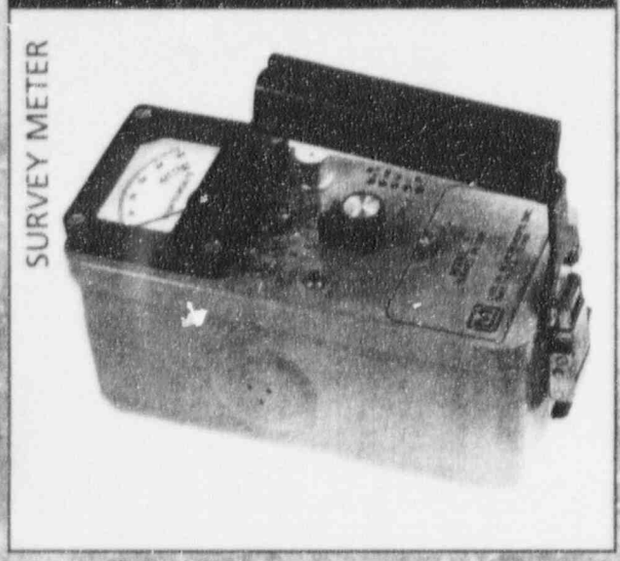
	44-7	44-9	44-40	44-88
DETECTOR	End window halogen quenched G-M	Pancake type halogen quenched G-M		
WINDOW AREA	6 cm^2 active 5 cm^2 open	15 cm^2 active 12 cm^2 open		
EFFICIENCY (4pi geometry)	2%-^{14}C; 10%-$^{90}S/^{90}Y$; 7%-^{239}Pu	5%-^{14}C; 22%-$^{90}S/^{90}Y$; 19%-^{99}Tc; 32%-^{32}P; 15%-^{239}Pu		
SENSITIVITY	Typically 2100 cpm/mR/hr	Typically 3300 cpm/mR/hr		
DEAD TIME	Typically 200 µs	Typically 80 µs		
CONSTRUCTION	Anodized aluminum housing	Aluminum housing	Lead housing*	Aluminum housing
SIZE	1.8"(4.6cm) diameter 5.8"(14.7cm)L	1.8"(4.6cm)H 2.7"(6.9cm)W 10.7"(27.2cm)L	4.5"(11.4cm)H 4"(10.2cm)W 6.5"(16.5cm)L	2.3 (5.7cm) diameter 2.8"(7cm)L
WEIGHT	1 lb (0.5kg)	1 lb (0.5kg)	5.5 lbs (2.5kg)	0.5 lbs (0.2kg)

*** Model 44-40-2 with aluminum cased lead shield is also available**

915-235-5494 • FAX 915-235-4672 • 800-622-0828 (USA)

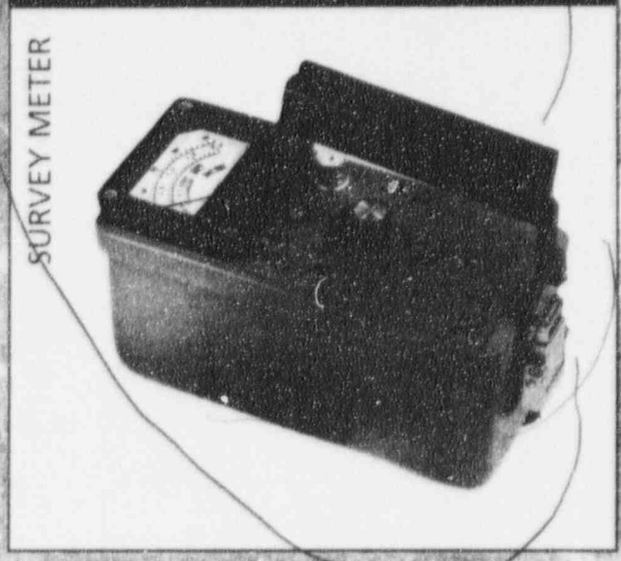
General Purpose Survey Meters

Model 3



Note: The Model 3 is also available with an alarm circuit. (Model 3A)

Model 14C

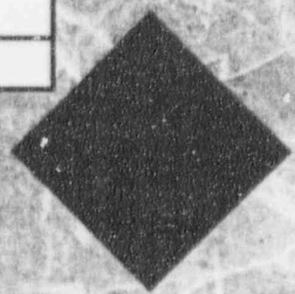


0-2,000 mR/hr Total Range

Common Specifications

COMPATIBLE DETECTORS: G-M, scintillation
THRESHOLD: 30 mV ± 10 mV
SIZE: 6.5" (16.5 cm)H X 3.5" (8.9 cm)W X 8.5" (21.6 cm)L
WEIGHT: 3.5 lbs (1.6 kg) including batteries

	MODEL 3	MODEL 14C
METER DIAL (others available)	0 - 2 mR/hr, or 0 - 5k cpm, BAT TEST	0 - 2 mR/hr and cpm, BAT TEST
MULTIPLIERS	X0.1, X1, X10, X100	X0.1, X1, X10, X100, X1000
INTERNAL DETECTOR	N/A	Energy compensated G-M (used with X1000 range only)
ENERGY RESPONSE	Dependant on detector used	Within ± 15% of true value between 60 keV - 3 MeV (internal detector only)
HIGH VOLTAGE	Ajustable from 200-1500 volts	900 V



MODEL 3500-5000 Gate Monitor	48-2721	36000.00
MODEL 3503 Radiation Detection Monitor	48-2145	2575.00
MODEL 3523 Gate Monitor	48-2732	5995.00
MODEL 3530 Waste Monitor	48-2312	3295.00
MODEL 3532 Waste Monitor	48-2483	4250.00
MODEL 3534 Waste Monitor	48-2477	7995.00

RESPONSE KITS

	PART NO.	PRICE
Response Kit with Model 14C, Model 44-9, Model 44-2	48-2653	1220.00
Response Kit with Model 2241-2, Model 44-9, Model 44-2	48-2829	1400.00

ALPHA DETECTORS

	PART NO.	PRICE
MODEL 43-1 Alpha Scintillator	47-1516	520.00
MODEL 43-2 Alpha Scintillator	47-1517	335.00
MODEL 43-5 50 cm^2 Alpha Scintillator	47-1521	420.00
MODEL 43-20 Gas Proportional Detector	47-1530	370.00
MODEL 43-44 50 cm^2 Alpha Air Proportional Detector	47-1169	130.00
MODEL 43-44-1 100 cm^2 Alpha Air Proportional Detector	47-2385	225.00
MODEL 43-65 50 cm^2 Alpha Scintillation Body Frisker	47-1441	425.00
MODEL 43-68 Gas Proportional Detector	47-2005	360.00
MODEL 43-90 100 cm^2 Alpha Scintillator	47-2448	650.00

ALPHA/BETA DETECTORS

	PART NO.	PRICE
MODEL 43-1-1 Alpha Beta Scintillator	47-2336	795.00
MODEL 43-2-2 Alpha Beta Scintillator	47-2003	395.00
MODEL 43-89 100 cm^2 Alpha Beta Scintillator	47-2430	750.00

BETA GAMMA DETECTORS

	PART NO.	PRICE
MODEL 44-1 Beta Scintillator	47-1531	370.00
MODEL 44-2 Gamma Scintillator	47-1532	370.00
MODEL 44-3 Low Energy Gamma Scintillator	47-1533	370.00
MODEL 44-6 Thin Wall G-M Detector	47-1535	130.00
MODEL 44-7 Thin End Window G-M Detector	47-1536	115.00
MODEL 44-9 Pancake G-M Detector	47-1539	175.00
MODEL 44-10 Gamma Scintillator	47-1540	750.00
MODEL 44-11 Integral Gamma Scintillator	47-1541	750.00
MODEL 44-12 Integral Well Scintillator	47-1542	750.00
MODEL 44-17 Gamma Scintillator	47-1547	675.00
MODEL 44-20 Integral Gamma Scintillator	47-1104	1450.00
MODEL 44-21 Beta/Gamma Scintillator	47-1560	405.00
MODEL 44-25 Pancake G-M Hand Frisker	47-1508	315.00
MODEL 44-26 Pancake G-M Foot Frisker	47-1509	405.00

MODEL 3500-5000 Gate Monitor	48-2721	36000.00
MODEL 3503 Radiation Detection Monitor	48-2145	2575.00
MODEL 3523 Gate Monitor	48-2732	5995.00
MODEL 3530 Waste Monitor	48-2312	3295.00
MODEL 3532 Waste Monitor	48-2483	4250.00
MODEL 3534 Waste Monitor	48-2477	7995.00

RESPONSE KITS

	PART NO.	PRICE
Response Kit with Model 14C, Model 44-9, Model 44-2	48-2653	1220.00
Response Kit with Model 2241-2, Model 44-9, Model 44-2	48-2829	1400.00

ALPHA DETECTORS

	PART NO.	PRICE
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MODEL 43-5 50 cm^2 Alpha Scintillator	47-1521	420.00
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MODEL 43-68 Gas Proportional Detector	47-2005	360.00
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MODEL 44-12 Integral Well Scintillator	47-1542	750.00
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MODEL 44-25 Pancake G-M Hand Frisker	47-1508	315.00
MODEL 44-26 Pancake G-M Foot Frisker	47-1509	405.00

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: _

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SONTRA MEDICAL, L.P.
RECEIVED DATE: 960626
DOCKET NO: 3034191
CONTROL NO.: 123369
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: #1500.00
CHECK NO.: 1295

3. COMMENTS

SIGNED Rebecca J. Brown
DATE 7/9/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ✓)

1. FEE CATEGORY AND AMOUNT: 3M $1,500

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE ✓

3. OTHER _____
_____

SIGNED D Brown
DATE 7/15/96

(46)
Log July 3
Remitter
Check No. 1295
Amount $1,500
Fee Category 3M
Type of Fee APP
Date Check Rec'd 7/5/96
Date Completed 7/15/96
By: D Brown