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Boehringer Ingelheim
Pharmaceuticals Inc.

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

MS 16
P-7

23 December, 2004

Re: Mail Control No 135568, NRC Letter Docket No. 03017101, Boehringer Ingelheim Pharmaceuticals, Inc. Request for Additional Information Concerning Application for Renewal of License

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Telephone (203) 798-9988

Dear Mr. Thompson:

This letter is Boehringer Ingelheim Pharmaceuticals, Inc.'s (BIPI) response to the NRC's request for additional information for the renewal application of License No. 06-19183-01.

1. ***Please identify special use facilities such as your waste facility and provide room drawings and descriptions of specialized equipment that will be utilized in these areas. You may re-submit previously provided documents if there are no changes.***

   BIPI provided the NRC with the following two letters describing the Regulated Waste Storage Building (RWSB):

   a) Letter to Mr. Thor Oberg, NRC, describing the plans and design for constructing the RWSB, Undated.
   b) Letter to Mr. Thor Oberg, NRC, in response to a request for additional information concerning the construction of the RWSB and in response to specific item numbers in NRC Information Notice 90-09, December 15, 1994.

   These letters are included in Attachment A. Since construction of the RWSB, there have been no changes to the structure or the material handling practices described. However, recent layout changes have taken place to accommodate storage needs. As such, a new map is also included

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NMSS/RGNI MATERIALS-002

in Attachment A. The restricted area is roped off and includes the Compactor Room, Freezer Room, Repack and Storage Area, and the interim storage units. The compactor has not been used in seven years and there are currently no plans to use it in the future. The laboratory has a hot work area near the hood. The fire suppression system, with seven CO_2 tanks, is located across from the Dry Active Waste (DAW) storage shelves.

The RWSB meets security and ALARA requirements. For security, the building is locked when not in use. Contamination and radiation surveys are performed monthly by Radiation Safety to maintain exposures ALARA.

2. ***In Item 9, under Facilities and Equipment, of your application, you respond by indicating the Radiation Safety Officer (RSO) evaluates the facilities to establish the appropriate facilities and equipment. Your license is of broadscope and authorizes many activities, therefore we are interested in your Radiation Safety Committee's (RSC) method of classifying the information you receive in an application to arrive at the appropriate facilities and equipment. Appendix K of NUREG-1556, Vol. 11 provides radionuclide toxicity and laboratory classification information which may be used. Additionally, Appendix L provides some useful guidance in identifying areas of concern. Please provide your method of classification.***

The Radiation Safety Office and the RSC evaluates all facilities and equipment used for work with radioactive material. Prior to performing any research, protocol applications are submitted to the RSO for review and the RSC for approval. Subsequently, the RSO and RSC evaluate facility and equipment necessary for the type of work being performed based on type, toxicity and quantity of byproduct material. With a few exceptions, most work at BIPI involves less than 10 mCi of tritium and carbon-14, and less than 5 mCi of sulfur-35, which are classified by the IAEA Safety Standard, Safety Series No.1, "Safe Handling of Radionuclides" (1973), as low and moderate radiotoxicity, respectfully. As such, laboratories at BIPI have the same restrictions applied to Type C (low radiotoxicity) laboratories. Specific requirements for Type C laboratories are as follows:

- All areas where radioactive materials are used are considered "restricted areas." This includes all laboratories and waste storage rooms. As is customary in all laboratories, a fire extinguisher, decontamination showers and eye wash stations are required. In addition, laboratories using radioactive materials, other than tritium, have a calibrated radiation meter available. The Radiation Safety Office keeps an inventory of the meters and their calibration due date and source checks. Monthly audits are performed in all restricted areas. These include removable contamination measurements (smears).
- Non-porous bench tops and open work areas are used when working with small quantities of radioactive materials that are not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Bench tops and open work areas are marked with yellow and magenta 'Radioactive Material" tape around

the work area. Shielding consists of lead in the form of plexiglass shields, L-shields and storage containers.

- Any materials that can become airborne or have the potential to spread contamination must be handled in fume hoods or biological safety cabinets. These enclosures are labeled with "Radioactive Material" signs.
- Remote handling tools, such as forceps, are used to provide distance in the handling of radioactive materials (ALARA). In protocol applications, Principal Radiation Users (PRUs) are required to obtain approval from the RSC of all containment, shielding, and handling devices that will be used in their research to ensure that they are appropriate for the type and quantity of materials used and the operations to be conducted.
- Food, beverages, and or cosmetics are not allowed in restricted areas. As such, designated areas are provided for personal belongings, food, beverages, and cosmetics.
- Significant modifications affecting restricted areas must have prior RSO review and RSC approval before commencement of such modifications.

The Radiosynthesis Laboratory is categorized as a Type A laboratory due to the levels of radioactive materials used. All of the Type C requirements apply to this area, along with additional personnel protective clothing, personnel monitoring and security measures. Shoe covers, safety glasses, gloves, and lab coats are required at all times. Prior to leaving the work area, personnel must frisk to prevent the spread of contamination outside of the laboratory. In addition, all doors to the laboratory must remain locked at all times. The PRU must provide access to anyone requesting entry, including maintenance and housekeeping.

During laboratory audits, the RSC evaluates laboratory and waste storage room conditions to ensure that equipment and facilities are adequate to protect health and minimize danger to life or property. In addition, the Radiation Safety Office performs continuous site walk-downs to monitor the laboratory conditions and ensure that all radiation workers are complying with the Radiation Protection Manual and the approved protocol.

In the case where a PRU would like to use a larger quantity or a byproduct material with a greater radiotoxicity, the classification of areas is evaluated to determine if more stringent facilities and equipment are necessary. As recommended by the IAEA Safety Standard, Series No. 1, conventional modern chemical laboratories with adequate ventilation and non-porous work surfaces may increase the upper limits of activity for Type C laboratories to the limits for Type B for toxicity in Groups 3 (moderate toxicity) and 4 (low toxicity).

3. ***Please provide a description of the animal handling and housing facilities where byproduct materials will be used. You may find Appendix H of NUREG-1556, Volume 7 as useful guidance on the information you should provide.***

BIPI does not use byproduct material at the animal handling and housing facilities. Animals to which labeled compounds have been administered are held in special

animal quarters separate from the general animal quarters until the animals are sacrificed and disposed of. The animals are housed within these designated areas of the laboratory where they are cared for by scientists who have received radiation safety training. Initial animal studies with carbon-14 or tritium labeled compounds will be done in rodents housed in sealed metabolism cages. At the conclusion of each animal study, the cages and other equipment, the floors, and the general area are surveyed and decontaminated to levels that allow release of the area for unrestricted use. All of the animals, their waste, and materials used are disposed of as low-level radioactive waste.

4. ***You have provided some general information on your safe use of radioactive materials and emergencies; however, more detail is needed. Additionally maintaining security of byproduct material should be addressed. Please refer to Appendix R of NUREG-1556, Volume 11 procedures that NRC has found acceptable and submit your procedures.***

General procedures for safe use, including security of materials and emergencies, have been developed as part of the Radiation Protection Manual. All PRUs are required to acknowledge these procedures as part of their radiation safety training.

A. Maintaining Security of Byproduct Materials

All radioactive materials at BIPI are stored in restricted areas (except for sealed radioactive waste drums awaiting shipment, which are kept in a dedicated area of the RWSB) within the guarded company complex. Laboratories and other rooms in which radioactive materials are used or stored are posted, "CAUTION RADIOACTIVE MATERIALS". Radioactive materials are kept under the control of the user who is required to store them in lockboxes in refrigerators when not in use.

The PRU is responsible for maintaining current and accurate records of the use and disposition of all radioactive materials that they receive. A "Record of Use and Disposition of Radioactive Material" form is used to record this information and to track radioactive materials until they are completely used and disposed. A separate form must be completed for every discrete sample of radioactive material received or transferred within BIPI, regardless of whether package monitoring is required.

A physical inventory of all radioactive materials is conducted at least every six months to confirm that the amount of radioactive material that BIPI possesses is within license limits, that PRUs do not possess more than their individual possession limits specified in their PRU applications, and that all materials are secure and accounted for. The computerized database containing the records of receipt is used to generate the list of all radioactive materials which have not been recorded as disposed. The Radiation Safety Office sends these lists to the responsible PRUs, who compare the list with the actual materials on hand, update the records as appropriate, and return them to the Radiation Safety Office. The computer database is updated, and reports are generated showing the amounts of each radionuclide currently in the possession of each PRU and the totals of each

radionuclide in the possession of BIPI. These are compared with the corresponding possession limits and a final report is issued to the RSC. Any discrepancies are investigated and resolved by the RSO and RSC to ensure that all radioactive materials are accounted for.

B. Waste Disposal Practices

Radioactive waste disposal at BIPI must conform to the specific requirements of 10 CFR 20.1301, 20.1302, Subpart K, other NRC regulations, DOT transportation regulations, the waste disposal broker, and the ultimate waste disposal site. All laboratory procedures involving radioactive materials are designed to minimize the volume of radioactive waste to the extent consistent with radiation safety and regulatory requirements. Specific waste disposal practices at BIPI are as follows:

- Step-lid cans and plexiglass waste containers are used for holding radioactive wastes in the laboratory until they can be transferred to the larger drums or to the RSO for disposal.
- Radioactive waste, both liquid and solid, are segregated by radionuclide. Short half-life nuclides are stored for a minimum of eleven half-lives, resurveyed, and disposed of as non-radioactive waste.
- Laboratory personnel deposit properly tagged and bagged DAW directly into 55-gallon drums. The waste is segregated by half-life less than 30 days, half-life greater than 30 days, carbon-14 and tritium.
- All aqueous wastes generated at BIPI are well within limits provided by federal regulations for the controlled release of water soluble or dispersible radioactive materials into a sanitary sewer system. However, BIPI has elected not to dispose of radioactive liquids, wash water, animal excretions or other wastes to the sanitary sewer.
- Liquid scintillation counter (LSC) waste that contains only tritium or carbon-14 is segregated from LSC waste containing other radionuclides. Category SX drums are limited to less than 0.05 uCi of tritium and carbon-14 per gram of medium, which may be averaged for the entire drum.
- Biological waste contaminated with radionuclides is packaged in opaque, heavy plastic bags by laboratory personnel. The addition of formaldehyde is prohibited, and no etiological agents are permitted in these containers. Laboratory personnel deposit the bags, labeled with the name of the PRU, the date, the radionuclide contained, and its quantity, in a dedicated freezer in the main radioactive waste room. When enough waste has accumulated in the freezer, the frozen bags are packed in a container for shipment by the waste contractor.
- Biohazardous materials are not permitted in radioactive waste drums. If a laboratory generates radioactive waste which is also biohazardous, the waste can be disposed as "biohazard radioactive waste".
- Radioactive wastes containing RCRA hazardous components are considered mixed wastes. Mixed wastes that cannot be readily treated to remove the hazardous components will be stored in the main radioactive waste room in plastic carboys (aqueous HPLC solvents) or glass jugs (non-

aqueous organic solvents and contaminated pump oil) until their disposal. The containers are labeled to show both the radionuclides and the chemical composition of the materials contained. This waste is maintained under the control of the Radiation Safety Office and is tracked in the radioactive materials inventory.

- Sealed drums are stored in the RWSB under the supervision of Radiation Safety. When the radioactive material in a drum has decayed to the point where shipment is warranted, the Radiation Safety Office arranges for the shipment. The drums are checked for proper labeling. A survey is made to ensure radiation levels are below environmental levels for decay in storage drums and below DOT transport limits for LSC drums. The Radiation Safety Office also prepares the required shipping manifest(s) and keeps copies of them on file until the NRC authorizes their disposal.
- Wastes that are allowed to decay to background to be disposed as non-radioactive are stored in a secure location and tracked in the radioactive materials inventory until they are discarded. They are stored for at least eleven half-lives, then surveyed with an appropriate survey meter to demonstrate that the level of radioactivity is equivalent to background. Records are kept of these surveys.

C. Contamination Controls and Area Monitoring

Radiation Safety makes routine surveys with swipes in all areas where radionuclides or radiation-producing devices are stored or used, including the radioactive waste storage area of the RWSB, to assure compliance with Title 10 of the Code of Federal Regulations, Part 20 (10 CFR 20). Any unposted area, accessible to personnel, which is found to have radiation levels requiring warning postings will be posted immediately. These surveys are performed monthly and records are retained by the Radiation Safety Office until the NRC authorizes their disposition.

PRUs are required to maintain records of contamination surveys. The Radiation Safety Office relies on the radiation and contamination surveys performed monthly by laboratory personnel for the detection and control of contamination. PRUs must ensure that such contamination surveys are performed at the end of each work day or experiment during which radioactive materials were handled, and the survey results must be documented (either positive or negative) in the laboratory notebook. Monthly contamination surveys of the entire laboratory and common areas are documented in a separate log book maintained for that purpose. Such records are kept until the NRC authorizes their disposition.

All work surfaces used for radionuclide work (bench tops, hood, floors, etc.) as well as storage areas and areas adjacent to permanent set-ups and sinks are to be protected with plastic-backed absorbent paper matting, stainless steel or plastic trays, uncracked glass plates, or other impervious materials. If disposable matting is used, it must be regularly dusted and must be discarded frequently (at least once a month) to prevent radioactive materials from accumulating and dusting off the

surface. If trays are used, it is advisable to line them with disposable matting as well. Trays, dry boxes, and surfaces covered with absorbent padding which are used frequently or routinely for active work with radioactive materials in normal form must be clearly marked with standard radiation caution signs or stickers.

Laboratory procedures must be designed to minimize the chance of dusting, aerosols, splashes, sprays, and spills. If possible, radioactive materials are to be handled as solutions rather than powders, and liquid transfers are to be made by pipetting rather than pouring. The work area and surrounding areas, including the floor and the work benches not protected by a disposable mat, are to be checked for contamination during work activities (if practicable) or whenever contamination is suspected, as well as upon completion of the work. Any significant contamination must be cleaned up promptly to prevent its further spread.

D. Use of Protective Clothing and Equipment

Labcoats, safety glasses and disposable gloves are required in all laboratories whenever handling radionuclides. The gloves must be changed whenever they become contaminated, worn, or torn. If there is a break in the skin below the wrist, a second outer pair of disposable gloves is used and changed frequently. Protective clothing outside of the laboratory areas or while eating, drinking, or applying cosmetics are not permitted.

As work is being performed, a survey meter equipped with a probe appropriate for the radionuclides must be used to monitor the work area and the hands (gloves) for contamination. Before leaving the laboratory hands, cuffs and lapels of lab coats and shoes must be frisked. Hands must be washed. If any contamination is found on the hands, they must be decontaminated. If any contamination is found on clothing, further surveys must be done to determine the extent of contamination and any contaminated clothing is disposed of as low-level radioactive waste.

E. Responsibilities for Radiation Protection and Regulatory Compliance

The Management of Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) has the ultimate responsibility for the radiation protection program. The objective of this program is to keep radiation exposures of personnel and radioactive contamination of the environment as low as reasonably achievable (ALARA). Adequate facilities will be provided for safe handling, storage, distribution, and disposal of radioactive materials. Managers are required to support and implement disciplinary or corrective actions recommended by the RSC.

Management established the RSC to develop, implement, and administer the BIPI radiation protection program within the regulations and guidelines of the NRC. The Chairman and the RSO are responsible for the overall direction and administration of the radiation safety program. They are the primary contacts with the NRC, which must approve any change of assignment of people to these positions. The RSC has the authority and the responsibility to develop, implement, maintain, and review the

radiation protection program to ensure compliance with government regulations; produce, maintain, revise, and distribute the Radiation Protection Manual which describes the radiation protection program; evaluate the training and qualifications of personnel who wish to use radioactive materials or ionizing radiation, authorize qualified users, provide ongoing training and review courses in radiation safety and experimental techniques for using radionuclides; and monitor, evaluate, and control the acquisition, handling, and disposal of radioactive materials and radiation-producing devices.

The RSO is responsible for the day-to-day administration of the radiation protection program as it is described in this Radiation Protection Manual. Adequate personnel, facilities, and equipment will be provided by Management to enable the RSO to implement and maintain radiation protection services required by the BIPI radiation protection program and government regulations.

Principal Radiation Users (PRUs) are senior laboratory personnel, usually laboratory supervisors, under whose direction work with radioactive materials and ionizing radiation is conducted. PRU's are responsible for ensuring that all personnel working with radioactive materials or other sources of ionizing radiation under their direction have been approved as RWs by the RSC; training personnel under their supervision in safe practices and procedures related to the operations of their laboratories, posting safety rules which are specific to their operations, and ensuring that all work with radioactive materials and ionizing radiation conducted under their supervision complies with the procedures described in the Radiation Protection Manual and with state and federal rules and regulations.

F. Personnel Monitoring

Whenever applicable, two kinds of devices are used to monitor RWs for exposure to external radiation. Film badges detect and measure whole-body radiation exposure, and TLD rings detect and measure exposure to the hands. The badges and rings are issued to RWs according to the criteria listed below and are required to be exchanged and analyzed monthly. Records are reviewed by the Radiation Safety Office and kept on file in the Radiation Safety Office for at least three years. They are then are transferred to BIPI's Records Retention Area where they are kept until the NRC authorizes their disposition.

Workers who are issued film badges will wear them while engaged in work with radioactive materials or radiation-producing devices. Those who are issued TLD rings are required to wear them while engaged in work for which the rings were provided. For work with unsealed ("normal form") radionuclides, rings must be worn under disposable gloves, and the sensitive part of the ring must be on the palm side of the hand, since that is where any radiation exposure is likely to be received.

Based on the NRC Regulatory Guide 8.32 and the amount of tritium handled at BIPI urine bioassay for Radiation Workers outside the Radiosynthesis Laboratory is not

required. However, the RSO may require any Radiation Worker to submit urine specimens at any time if they are suspected of possible accidental contamination. In addition to tritium, Radiation Workers who use more than 30 mCi of carbon-14 or 40 mCi of sulfur-35 in a month must be monitored by urine bioassays.

G. Handling of Radionuclides and Shielding

Specific handling techniques to minimize exposure will be established by PRUs with the concurrence of the RSO. These techniques and safety measures will be appropriate for the type and quantity of nuclide being used. If necessary, radioactive sources, stock solutions, and waste containers in the laboratories will be shielded in such a manner that the radiation levels in any occupied area will expose individuals in the area to as little radiation as reasonably achievable.

Radiation exposure may be attenuated or eliminated by placing appropriate shielding materials between the radiation source and the worker. Different kinds of shielding are required to attenuate or eliminate different types of radiation. The area surrounding shielded material must be checked with a calibrated survey meter to ensure that the amount of shielding being used is sufficient to reduce radiation levels to those specified in federal regulations.

Except in multi-mCi amounts, weak beta emitters such as tritium, carbon-14, and sulfur-35 do not pose an external radiation hazard and do not require shielding. Only the Radiosynthesis Laboratory and Ultra High Throughput Screening Laboratories are permitted to have more than 15 mCi of any given radionuclide.

Strong beta emitters such as phosphorus-32, as mentioned above, pose serious radiation hazards. Work with such nuclides will be designed to minimize exposure to the penetrating beta radiation as well as minimize generation of and exposure to bremsstrahlung. Work with phosphorus-32 will be performed as much as possible behind a shield constructed with a minimum thickness of 3/8 inch clear plexiglas. In addition, small plexiglas shields will be used as much as possible around vials, syringes, *etc.*, which contain most of the activity. As much as possible, tongs will be used to minimize the dose to the hands.

Gamma emitters such as chromium-51 and iodine-125 must be shielded with dense material, such as lead, of sufficient thickness to reduce the radiation field at the worker's body to as low a level as reasonably achievable. At the low levels typically used at BIPI, adequate shielding can usually be achieved with thin (1-3 mm) sheets of lead, but in some cases lead bricks up to 5 cm thick may be needed.

H. Emergency Procedures

While any spills or splashes of radioactive materials should be avoided insofar as possible, small spills involving small amounts of radioactive materials may occur occasionally. In most cases, the workers involved can quickly and easily clean them up and continue with their work. When the work is completed, or at the end

of the workday, the area should be surveyed for contamination to ensure that it is clean.

In the event of any spill which cannot be readily and completely contained and decontaminated by the laboratory worker(s), the area of contamination must be clearly marked, and the PRU and the RSO must be notified immediately. These individuals will then post and isolate the contaminated area or equipment and supervise clean-up of the spill.

In the event of injury to a person working with radionuclides, the first concern is to administer necessary first aid medical treatment. Every reasonable effort will be made to minimize the spread of contamination or exposure of additional personnel to radiation, but these considerations must not interfere with aiding the injured person. The supervisor of the laboratory and the RSO must be notified immediately. In addition, if the medical problem appears minor, the company nurse must be called. If the medical problem appears major, the BIPI emergency number must be called.

All laboratories in which radioactive materials are used are posted with the radioactive materials warning signs, and also with the names and telephone numbers of workers who can be contacted in such emergencies. Security personnel have been instructed to call those laboratory workers immediately in the event of an emergency occurring in their laboratory areas, and also to notify the RSO or a member of the RSC, who will respond and help to supervise emergency procedures with respect to radiation safety concerns.

If the RSC determines that an emergency involving radiation or radioactive material occurred as a result of negligence or disregard of the procedures and rules stated in this Manual, it may suspend operations in the affected laboratory area and/or revoke or suspend the PRU and/or RW authorization(s) of the individual(s) involved.

5. ***Please note that you have indicated you will decay in storage Sr-90. Sr-90 has a greater than 120 day half life. Please clarify.***

Strontium-90 was mistakenly added to the list of radionuclides that will be decayed in storage at BIPI. In actuality, Sulfur-35, which has a half-life of 87.4 days, is used at the facility.

6. ***Submit a description of the RSC program criteria for review of protocols, permits issued to authorized users.***

A prospective authorized user must submit the appropriate protocol application to the RSC via the RSO. The RSO reviews the application and discusses clarifications, corrections, or modifications with the applicant. Once revised, the RSO presents the protocol to the RSC for review and approval at the next RSC meeting. The applicant may not perform any work with radioactive materials or ionizing radiation until the

RSC has actually approved the application. Approved applications are signed by the Chairman of the RSC and the RSO and copies are returned to the applicants as notification of approval.

If proposed work covered by an application is very urgent, temporary approval may be given by the RSO or the Chairman of the RSC. In such a case, official approval must be obtained from the RSC within one month, or work covered by the application must stop immediately. If any conditions represented in approved applications change, a new application must be submitted immediately.

All authorizations are subject to review at any time by the RSC, which may require PRUs to submit new protocol applications whenever the RSC considers that necessary to maintain effective oversight of the radiation protection program.

7. ***Submit a description of the RSC program criteria for review and approval of new users.***

The RSC expects applicants to have sufficient training and experience with radioactive materials and/or sources of ionizing radiation to engage knowledgably and safely in the proposed activities. The RSC evaluates the general education and experience of the applicant and their experience with sources of radiation. To ensure that all applicants have a basic understanding of radiation protection prior to working with sources of radiation, applicants are required to complete the computer-based Radiation Worker Training and read the Radiation Protection Manual. Following the course, a written test is given to every participant. The test is graded and the percentage passing for each test question is correlated to give feedback to the RSC. In addition, PRUs are responsible for training all personnel working under their supervision in safe practices and procedures related to the operations of their laboratories. This entails at least two supervised work sessions on the protocol to be used before any applicant is allowed to work unsupervised. Annually and whenever appropriate, the RSC may require individual Radiation Workers to repeat the course as "refresher" training.

8. ***If you would like Ni-63 as foils or plated sources listed separately, then please identify the sealed source model numbers and manufacturers for those Ni-63 foils or plated sources you would like to possess.***

BIPI no longer is in possession of Ni-63 foils. The Ni-63 foil used at BIPI in neutralization of charged aerosol particle experiments, was manufactured by CH Technologies of Westwood, NJ. During a recent inspection, it was discovered that the foil was unaccounted for. Attachment B includes the inspection report prepared by Radiation Safety and describes the efforts undertaken to recover it.

9. ***10 CFR 30.35 (e) indicated cost estimates for decommissioning must be adjusted every three years. Please review your previously submitted cost estimate for decommissioning and provide the required information for any changes that may need to be made.***

A revised cost estimate for decommissioning is presented in Attachment C. The supporting financial assurance documents will be provided, upon receipt, in a separate letter.

Thank you for the extension on responses to the RAI. Should you have further questions or comments, please contact me at (203)798-5136 or Patricia Lopez, Radiation Safety Officer at (860) 210-3058.

Sincerely,

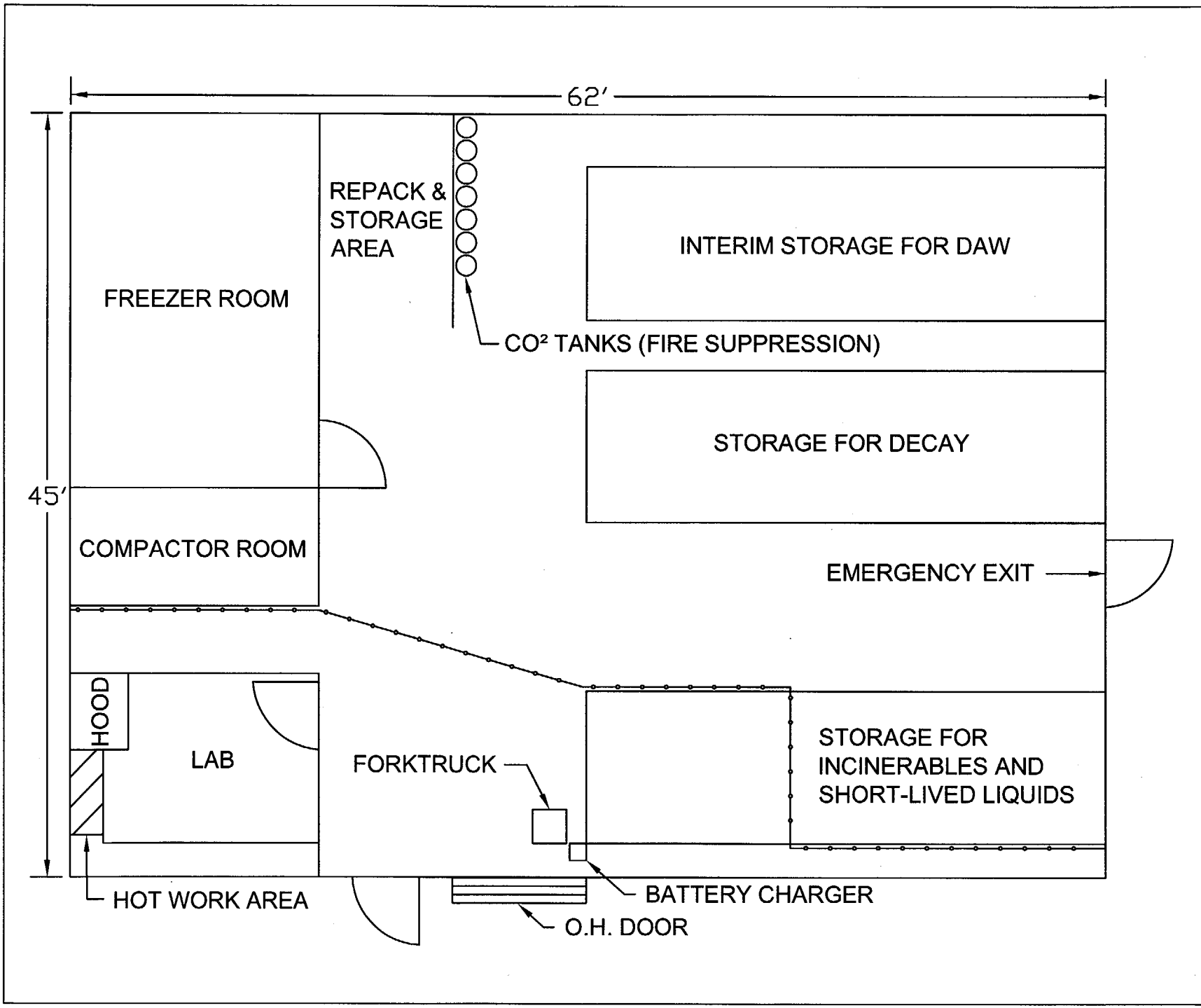
Karl D. Hargrave

Karl D. Hargrave, Ph.D.
Chairman, Radiation Safety Committee

KH/kb
Enc

cc: Art Slesinger
Ken Modrovsky
Patricia Lopez

Attachment A
Map and Letters Describing the Regulated Waste Storage Building



DOCUMENT CONTROL NO.

REVISION NO.

PROJECT: BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. RIDGEFIELD, CT.

DRAWING: RADIOACTIVE WASTE STORAGE BUILDING

SCIENTECH
SCIENTECH, LLC.
THE BLEACHERY
143 WEST STREET
NEW MILFORD, CT. 06776
(860) 210-3000

PROJECT # 23543

FILENAME: 23543_RWSB

SCALE: N.T.S

DATE: 12/01/04

BY: DT

CK: PL

FIGURE # 1

Boehringer Ingelheim

Boehringer Ingelheim
Pharmaceuticals, Inc.
a subsidiary of
Boehringer Ingelheim Corporation
900 Ridgebury Rd
P.O. Box 368
Ridgefield, Connecticut 06877

Mr. Thor Oberg
United State Nuclear Regulatory Commission
Region I
475 Allendale Road
King Of Prussia, Pennsylvania 19406-1415

Ref: NRC Materials License No. 06-19183-01

Dear Mr. Oberg,

This letter presents information requested for the renewal of the above referenced license.

Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) is sited in Connecticut which is a member of the Northeast Compact. As the State of Connecticut does not have plans to build a Low Level Radioactive Waste (LLW) interim storage facility before the Barnwell facility closes to out-of-compact generators on June 30, 1994, BIPI plans to implement waste handling program of which interim storage is a part. BIPI understands that storage is not a substitute for disposal. For information purposes only, BIPI's waste currently consists of labware, solutions, solvents and animal carcasses used in the research and development of new drug compounds. The radioactive component generally consists of low activity beta emitters with some short lived gamma emitters. BIPI's Radiation Safety Office is making every effort to guide researchers toward practices that lend themselves to disposal. For example, incinerable labware, shorter halflife nuclides and non-radioactive tracers are disposal options that will be used by researchers whenever feasible. However, some waste will be generated and will need to be stored in the interim. BIPI has evaluated its annual waste generation and has formulated a plan to store its LLW onsite for a minimum of 5 years in a dedicated building which, at this writing, has tentatively been named the Regulated Waste Storage Building (RWSB), until a facility is opened in Connecticut. The following documentation is submitted in support of this plan.

USNRC Information Notice 90-09 was used as the basis for the design of the RWSB. BIPI understands that storage is not a substitute for disposal. At this writing, the RWSB is in the Architectural and Engineering phase and will be going out to bid shortly. As the footprint of the RWSB may change due to construction considerations, Attachment 1 is being provided for information purposes only. However, the internal layout of the building will contain areas for waste compaction, waste repackaging, frozen animal carcasses and bulk waste storage. The bulk storage will consist of a decay-in-storage area, an incinerable area and an interim storage area. Compliance with 90-09 will be maintained.

For example, when stored, the waste will be packaged ready for disposal, the ability exists to repackage waste, the waste will be shielded from the elements and the

RWSB racking layout provides for inspection of storage containers as well as the ability to expand or contract specific storage areas as research waste generation needs dictate.

For example, decay in storage waste will be packaged for ease of handling on a first in-first out basis. Liquid waste will be packaged in shatter-proof containers. Solid waste will be packaged as required for local incineration, disposal as ordinary trash or biohazard waste disposal.

For example, incinerables will be packaged according to the requirements of the contracted facility. BIPI will only contract with vendors licensed to incinerate radioactive material. For information purposes only, BIPI's current broker is U.S. Ecology. For information purposes only, incinerable waste is packaged as required by SEG, a Tennessee licensee. DAW that will be in interim storage will be packaged as required for LLW disposal. For information purposes only, BIPI DAW is currently packaged as required by the Barnwell, SC disposal facility.

The RWSB will be designed to meet 90-09 fire protection and ventilation requirements. For information purposes only, the architectural plans call for the fire protection to be provided by a CO_2 deluge system and atmosphere to be tempered to 50° F in the winter and ambient temperature in the summer with a 2500 cfm ventilation system.

The RWSB will be designed to meet 90-09 security and ALARA requirements. For security, the building will be locked when not in use. For information purposes only, the architectural plans also call for alarms to register in a security office if an intrusion occurs or if cooling fails. Contamination and radiation surveys will be performed as required to maintain exposures and releases ALARA based on when the facility is used. The appropriate equipment will be available to perform surveys. For example, G-M survey meters are available to perform radiation surveys and a LSC is available to perform contamination surveys. For example, G-M survey stations will assess personnel contamination after work in the building is completed. Air samples will be performed whenever the type of radionuclide being stored, the containment method and personnel presence requires it. BIPI will also conform to NRC and DOT survey regulations before a package is removed from the RWSB for shipment.

BIPI feels that its current possession limits are adequate for the generation of waste for the next 10 years. BIPI has requested an increase in the limit for ^{3}H to 50 Curies to accommodate the need of radiosynthesis researchers. The radiosysthesis laboratory is will be attempting to limit the tritium waste generated by building a tritium recovery system. Once in operation, this system will recycle amounts of tritium that would put BIPI over its current activity limit for tritium.

In using decay-in-storage as a disposal option, the Radiation Safety Committee has approved the building design and capacity based on isotopes with halflives less than 88 days (^{35}S). Therefore, a container of ^{33}S would be held for 10 halflives (approx. 2.5 years) before being disposed of as non-radiological waste. Any nuclides with halflives less

than 88 days (for example, ^{45}Sc (83 days) or ^{85}Sr (64 days)) would be segregated and held for appropriate 10 halflife periods.

As BIPI plans on breaking ground for this building within 1 month, I would ask that you contact me immediately to discuss any questions you may have concerning the preceding statements. I can be reached at 203-791-6270 between 8:30 a.m. and 4:00 p.m. EST.

Thank you for your considerations in this matter that will expedite BIPI's RWSB coming on-line in a timely and effective manner.

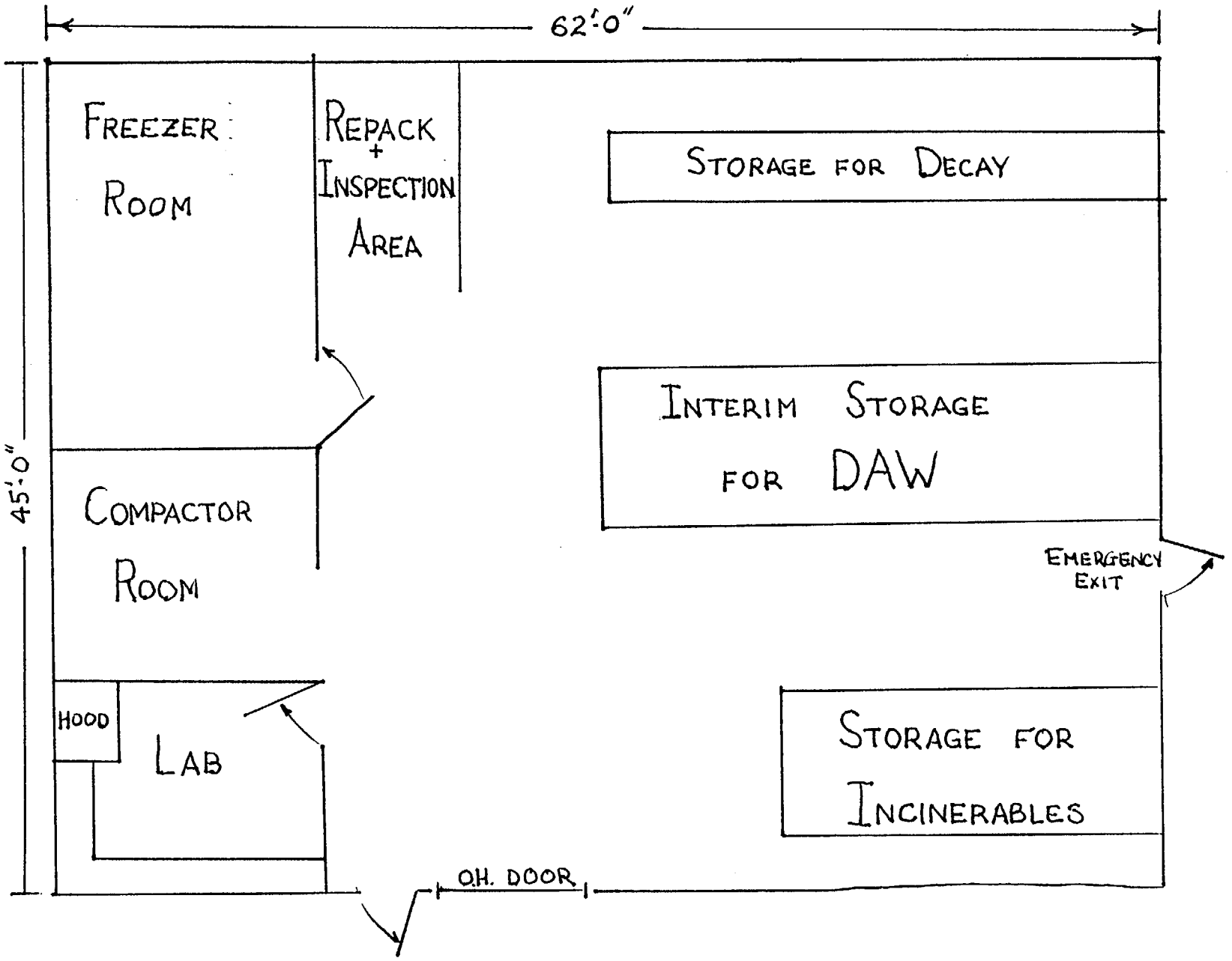
Sincerely Yours

Vincent Chase, RSO
Boehringer Ingelheim Pharmaceuticals, Inc.

Attachment: RWSB Footprint

Copies: 2

CC: J. Keirns, Ph.D., Chairman, RSC
A. Spak, Ph.D.
A. Slesinger


62'-0"
45'-0"
FREEZER ROOM
REPACK + INSPECTION AREA
STORAGE FOR DECAY
INTERIM STORAGE FOR DAW
COMPACTOR ROOM
EMERGENCY EXIT
HOOD
LAB
STORAGE FOR INCINERABLES
O.H. DOOR

Boehringer Ingelheim

Boehringer Ingelheim Pharmaceuticals, Inc.
a subsidiary of
Boehringer Ingelheim Corporation
900 Ridgebury Rd.
P.O. Box 368
Ridgefield, Connecticut 06877

December 15, 1994

Mr. C. Thor Oberg
Research and Development Section
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

REF: Control Number 120482

Dear Mr. Oberg;

This letter is Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) response to your letter of October 11, 1994 (your letter). The item numbers that follow refer to those in your letter.

1. Construction of the Regulated Waste Storage Building (RWSB) has been completed and the building is ready for use.

2. Sulfur-35 and Scandium-46 are the two nuclides with halflives greater than 65 days which BIPI intends to hold for decay-in-storage (DIS).

3. The response to this item is given in the format indicated in Information Notice 90-09, Attachment 1, February 5, 1990 which you included in your letter.

   1a. No possession limit increases are anticipated.

   1b. Because BIPI's materials license is Broad Scope, Type A and is applied to a research and development (R&D) facility, the following activity estimates, are based upon historical data. However, since R&D waste generation is not dictated by routine processes, such as those in nuclear power plants and nuclide production facilities, changes may be expected based upon the demands of R&D. Therefore, the following estimates are provided for information purposes only. The estimated maximum amount of Low Level Radioactive Waste (LLW) activity and volume to be stored by nuclide are:

Nuclide	Est. Max. Activity	Est. Max. Volume
^{3}H	10,000 milliCuries	309 cubic feet
^{14}C	48 "	243 "
Halflife less than 30 day (LTT)	34 "	96 "
Halflife greater than 30 days (GTT)	33 "	103 "

An estimate of the activity fractions for the LTT waste is 53% for ^{32}P, 46% for ^{33}P and 1% for ^{99m}Tc, ^{111}In and ^{51}Cr, combined.

An estimate of the activity fractions for the GTT waste is 66% for ^{35}S, 33% for ^{125}I and 1% for ^{85}Sr, ^{46}Sc and ^{141}Ce, combined.

1c. All waste will be Class A as either a solid or liquid. No physical processing is planned while waste is being stored on BIPI's site. Radiological waste is not to have other properties.

1d. For information purposes only, at this writing, there is approximately 120 cubic feet of Class A waste in the RWSB.

2a. Disposal capacity is no longer available and onsite storage has begun.

2b. For information purposes only, as per personal communication with Connecticut Hazardous Waste Management Service, waste will be stored at the proposed Connecticut LLW storage site which is scheduled to open by January 1, 2000.

2c. For information purposes only, BIPI will ship waste to the facility as soon as possible after it opens and should be able to complete transfer in one shipment.

3a. See blueprints in Attachment 1.

3b. For information purposes only, it is estimated that the RWSB would be able to hold approximately 85,000 cubic feet of LLW. The estimated annual LLW waste generation rate is 6,700 cubic feet. The annual waste generation rate does not include the removal rate for DIS.

3c through 3g, inclusive. See blueprints in Attachment 1.

3h. The Northeast Section of the United States is not seen as being vulnerable to the natural hazards described in this section. The building is not adjacent to any industrial operations and is seen as a typical warehouse operation.

4a. For information purposes only, the dry LLW for DIS will be stored in 55 gal cardboard drums suitable for incineration. Liquid LLW will be stored in either 1 gal plastic bottles or 30 gal plastic drums. ^{3}H and ^{14}C dry waste will be stored in metal 55 gal drums. No material in any container is expected to impact on package integrity. The expected storage life of the containers is for the life of the facility or, in the case of DIS, until the nuclides in the packages have decayed past 11 halflives.

4b. For information purposes only, packages are to be physically inspected on a six month basis. All sides of a package are to be inspected.

4c. As the majority of nuclides used at BIPI are low activity concentration beta emitters, remote handling equipment would not be applicable.

5a. For information purposes only, a forklift and ladders are available to place materials in their storage locations. The ladders will serve to aid in inspecting and performing contamination surveys. Surveys are to be performed on a monthly basis. Surveys will include common areas and equipment as well as a random survey of packages. Posting is in accordance with 10 CFR 20.203.

5b. For information purposes only, as it is anticipated that BIPI R&D operations will remain dedicated to pharmaceutical research. Therefore, increased exposure rates and shielding are not anticipated as nuclide concentrations should remain consistent with laboratory practices.

5c. For information purposes only, BIPI has a site specific emergency response telephone number. Upon activation, medical, security and safety departments interact with the initiator

to activate the correct response person or team (medical, spill, etc.). Fire suppression systems are tied in directly to local fire departments.

5d. For information purposes only, BIPI employs a system that includes receipt/inventory forms which are loaded into a computer database. Once waste is generated, a system of inventory tags is used to track the movement of waste from the laboratory. Tag information is loaded into a computer spreadsheet as it is consolidated into drums. The spreadsheet is used calculate DIS release dates and identify drums.

6. For information purposes only, all laboratory personnel receive Radiation Safety Refresher Training every two years. Dedicated personnel who handle waste in the RWSB, which is currently one person, also receive refresher training every two years and on the job training from the RSO.

7. A financial assurance plan has been submitted and accepted by the NRC.

8. BIPI possession limits do not exceed the limits specified in Subsections 30.32(i)(1).

4. For information purposes only, mixed waste is typically generated only by the Radiosynthesis Laboratory on an infrequent basis. These wastes will not be stored in the RWSB as it is not designed for the storage of flammable liquids.

5. For information purposes only, the following controls which are planned to prevent accidental incineration of LLRW:

   a. inventory tags are to be attached to each bag by the waste generator

   b, bags and tags are consolidated by the Radiation Safety Office and the tag information loaded in a computer database

   c. all DIS waste will be held for 11 halflives

   d. DIS waste will be stored in a separate area from waste that is stored for the extended interim period.

   e. any waste that is to leave the RWSB will be surveyed

6. The acronym DAW stands for Dry Active Waste.

Thank you for your assistance in this matter.

Sincerely,

Vincent Chase, CHP
Radiation Safety Officer

Attachment 1

Contains:

One page of text
10 Blueprints

This attachment contains documents which are provided in response to specific item numbers in USNRC Information Notice 90-09, February 5, 1990, Attachment 1 (90-09 Att. 1).

The structures and equipment in the building as constructed may differ slightly from the blueprints in this attachment. Therefore, any documents in this attachment are provided for information purposes only.

The blueprints reference 90-09 Att. 1 as follows:

Item Number (90-09 Att. 1)	Drawing Number(s)
3.a.	C-1, A-1
3.c.	A-2, A-3, F-1
3.d.	Spec-1, E-3, E-3
3.e.	Spec-2, M-1, E-2, E-3
3.f.	Spec-2, E-3
3.g.	Spec-2, M-2

Attachment B
Inventory Inspection Finding for Ni-63 Foil Strip

Boehringer Ingelheim

RADIATION SAFETY OFFICE

Date: 12-07-2004

To: Patricia Lopez (RSO)
Radiation Safety Committee

From: Ken Modrovsky

Subject: **Inventory Inspection Finding for Ni-63 Foil Strip**

As required by BIPI's Nuclear Regulatory Commission License (NRC) No. 135568, the Radiation Safety Office is in the process of performing the biannual radioactive isotope inventory.

BIPI was in possession of a 10 mCi Nickel-63 (Ni-63) strip used in 1996 for aerosol technology research projects. The Ni-63 strip was manufactured by CH Technologies, Inc. of Westwood, New Jersey and was only used for eight months. Afterwards, the machine was stored within a safety cabinet in Laboratory 7310.

The Principle Radiation User (PRU) who is responsible for the foil strip has reported to the Radiation Safety Office that the aerosol device containing this Ni-63 foil strip is missing. The manager of Laboratory 7310 stated that when he moved in October of 2003 into Laboratory 7310 he placed all unwanted equipment in the hallway for disposal.

A discussion with Ms. Lopez (RSO) was conducted immediately after the Ni-63 source was discovered to have been misplaced. Ms. Lopez reviewed Title 10 of the Code of Federal Regulations (CFR), Section 20 which states that the quantity for reporting lost Ni-63 sources to the NRC is 100 mCi. As such, it is not necessary to write a formal report to the NRC. While the misplaced Ni-63 source is exempt from NRC reporting requirements, Radiation Safety immediately launched a site-wide storage area and laboratory investigation for the device. In addition, interviews were conducted with all personnel who were working in the vicinity of the source or may have handled it once it was placed in the hallway. The extensive search yielded no conclusive information of the whereabouts of the source. Based on historical information, all equipment placed in the hallway was disposed of. As such, it is suspected that the source was inadvertedly sent to this facility.

Recommended Course of Action as dictated by the RSO:

1. Additional searches will be conducted in an attempt to locate the source. Possible avenues of disposal will be further investigated.
2. A Radiation Safety Committee meeting will be held to review equipment handling procedures to ensure that such situations do not occur in the future.
3. A discussion with the PRU responsible for the safekeeping of the source will occur to remind him of his responsibilities when working with radioactive materials.

Regards,

Ken Modrovsky
Radiation Safety Specialist

Attachment C
Decommissioning Cost Estimate

Cost Estimate for the D&D of Boehringer Ingelheim Pharmaceuticals, Inc. in 2004 Dollars

	Task	Cost Estimate
1	*Mobilization* Travel to Site Procurement of Supplies and Rental Equipment	$ 16,250
2	*Decontamination of Laboratories* Scoping and Characterization Surveys Radiosynthesis Laboratory Decontamination Other Restricted Area Decontamination Remedial Action Surveys	$ 130,000
3	*Laboratory Analysis Costs* Waste Profiling QA Samples Analysis	$ 6,500
4	*Final Status Survey* Survey of Laboratories Survey of Radioactive Waste Storage Building Survey of Other Restricted Areas	$ 84,500
5	*Shipping and disposal of LLRW* Purchase of Container(s) Transportation to Waste Disposal Site Burial Fees	$ 65,000
6	*Demobilization* Travel from Site Return of Rental Equipment	$ 6,500
7	*Report Preparation and Submittal*	$ 16,250
	TOTAL	**$ 325,000**