KENNY C. GUINN
Governor

CHARLOTTE CRAWFORD
Director

YVONNE SYLVA
Administrator

MARY E. GUINAN, M.D., Ph.D.
State Health Officer

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
HEALTH DIVISION
BUREAU OF HEALTH PROTECTION SERVICES

00 MAY -8 PM 2:39
OSP

March 1, 2000

Mark R. Shaffer
State Agreements Officer
U.S. Nuclear Regulatory Commission
611 Ryan Plaza Dr., Suite 400
Arlington, TX 76011-8064

Dear Mr. Shaffer:

Enclosed is a Nevada licensee's request for clarification of a waste disposal question. We would appreciate knowing the NRC's position on this issue.

If you have any questions, please contact this office.

Sincerely,

Larry Boschult
Radiological Staff Specialist
Radiological Health Section
Deputy Food and Drug Commissioner
Bureau of Health Protection Services

Enclosure

LB\ram\nrc waste disposal question

☐ Bureau Administration
1179 Fairview Drive, Ste. 201
Carson City, NV 89701-5405
(775) 687-6353
Fax (775) 687-5197

☐ Public Health Engineering
1179 Fairview Drive, Ste. 101
Carson City, NV 89701-5405
(775) 687-4754
Fax (775) 687-5699

☐ Drinking Water
State Revolving Fund
1179 Fairview Drive, Ste. 204
Carson City, NV 89701-5405
(775) 687-4750
Fax (775) 687-3218

☑ Radiological Health
1179 Fairview Drive, Ste. 102
Carson City, NV 89701-5405
(775) 687-5394
Fax (775) 687-5751

☐ Environmental Health
1179 Fairview Drive, Ste. 104
Carson City, NV 89701-5405
(775) 687-4750
Fax (775) 687-5751

☐ Health Protection Services
620 Belrose Street, Ste. 101
Las Vegas, NV 89107
Engineering and Food
(702) 486-5068
Radiological Health
(702) 486-5280
Fax (702) 486-5024

☐ Health Protection Services
850 Elm Street
Elko, NV 89801-3349
(775) 753-1138/1140

☐ Health Protection Services
475 W. Haskell Street, Rm. 38
Winnemucca, NV 89445
(775) 623-6588

☐ Health Protection Services
155 N. Taylor Street, Ste. 199
Fallon, NV 89406-3324
(775) 423-2281

☐ Health Protection Services
P.O. Box 939
Ely, NV 89301-0939
(775) 289-3325

☐ Health Protection Services
P.O. Box 667
Tonopah, NV 89049-0667
(775) 482-3997

☐ Health Protection Services
250 N. Highway 160, Ste. 5
Pahrump, NV 89048
(775) 751-7415

UNIVERSITY OF NEVADA RENO

Environmental Health and Safety Office
Mail Stop 328
Reno, Nevada 89557
(775) 327-5010
FAX: (775) 784-4557

February 7, 2000

Larry Boschult, Radiation Staff Specialist
Radiological Health Section, State Health Division
1179 Fairview Dr., Room 102
Carson City, Nevada 89701-5405

RE: Clarification of General Licensed Medical Testing Kit (Exempt Quantity) Material Disposal

Dear Mr. Boschult:

The State Health Laboratory (SHL) has become part of the UNR School of Medicine; thus their use of radioactive materials is now governed by the provisions of our Type A License. SHL has been using the BACTEG tuberculosis testing kits for over 10 years. Becton Dickinson Microbiology (BDM), 7 Loveton Circle, Sparks, MD 21152, manufactures and distributes the kit under a General License from NRC. A kit contains an exempt quantity of C-14 and any person may purchase, use, transfer, and own a testing kit without a license.

The kit information:

Radioactivity: Carbon-14 in liquid form, 4 microcurie average (less than 10 microcurie)
Weight: about 40 grams (one weighed 38.9 gram)
Container: 40-50 ml capacity glass vial
Contents: cell growth medium (no hazardous material)

Human sputum is injected into the kit using a needle, incubated, and analyzed for presence of $^{14}CO_2$ by automated instrument. The kit is never opened during the entire process. There is no direct human contact with C-14 as long as the kit is intact.

Two disposal methods suggested by the manufacturer are sanitary discharge or to treat it as laboratory waste after autoclave sterilization. For the purpose of transportation, the US DOT defines any material with specific activities greater than 0.002 microcurie per gram to be radioactive material. The BACTEC kit is 0.1 microcurie per gram and is, therefore, "radioactive material" according to US DOT. The manufacturer's instructions to discard the used kits into laboratory trash ignores the fact that a used kit is technically radioactive material. We believe that most kit use facilities do not have their own landfill, therefore, waste material must travel public highways to reach a landfill. To transport such material requires packaging and labeling in accordance with the US DOT regulations. Neither requirements are met when vials are treated as laboratory trash.

We would appreciate knowing your office's position regarding regulations on this issue: 1) Can used BACTEC TB testing kits be disposed of as laboratory trash? 2) If the vials cannot be disposed of as laboratory trash, how should they be processed for disposal? 3) Is BDM providing correct disposal methods to their kit users? 4) Is BDM authorized to suggest such disposal methods?

Thank you for your attention in this matter. Please call me at 784-4540 if you have any questions.

Sincerely,

Myung Chul Jo, RSO

Enclosure: MSDS, sections of user manual, and package insert

cc: Dr. Oberg
Dr. Simmonds

Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 02/01/2000 Reviewed on 12/17/1999

1 Identification of substance:

· **Product details:**

· **Trade name:** BACTEC #12 Mycobacterium Medium

· **Article number:** 442004, 4402004

· **Manufacturer/Supplier:**
In the Continental United States call:
BD Biosciences
7 Loveton Circle
Sparks, MD 21152
Tel: (410)771-0100 or (800)638-8663

Outside the United States call:
Becton Dickinson France SA
Regulatory Compliance Dept.
BD Biosciences Europe
11 rue Aristide Berges BP 4
38800 Le Pont De Claix France
Tel: 33 4 76 68 36 36

· **Information department:** Technical Services

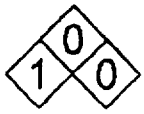
2 Composition/Data on components:

· **Chemical characterization:**
CAS No. Description:
Not applicable

· **Chemical characterization**
· **Description:** Mixture consisting of the following components.
Dangerous components:
carbon 14

3 Hazards identification

· **Hazard description:**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200 and the European Directive 91/155/EEC, 88/379/EEC, and 67/546/EEC.
· **NFPA ratings (scale 0-4)**



Health = 1
Fire = 0
Reactivity = 0

4 First aid measures

· **General information** Immediately remove contaminated clothing.
· **After inhalation**
Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Immediately rinse with water.

(Contd. on page 2)

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #12 Mycobacterium Medium

(Contd. of page 1)

· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing** If symptoms persist consult doctor.

* 5 **Fire fighting measures**

· **Suitable extinguishing agents**
CO2, extinguishing powder or water spray. Fight larger fires with water or alcohol resistant foam.
· **Special hazards caused by the material, its products of combustion or resulting gases:**
During heating or in case of fire poisonous gases are produced.
· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

* 6 **Accidental release measures**

· **Person-related safety precautions:**
Wear protective equipment. Keep unprotected persons away.
· **Measures for environmental protection:** Wipe up with damp sponge or mop.
· **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
· **Additional information:** No dangerous substances are released.

7 **Handling and storage**

· **Handling**
· **Information for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
· **Information about protection against explosions and fires:**
No special measures required.

· **Storage**
· **Requirements to be met by storerooms and receptacles:**
No special requirements.
· **Information about storage in one common storage facility:**
Store away from oxidizing agents.
· **Further information about storage conditions:** None.
· **Class according to regulation on flammable liquids:** Void

8 **Exposure controls and personal protection**

· **Additional information about design of technical systems:**
No further data; see item 7.

Components with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:**
The lists that were valid during the creation were used as basis.

· **Personal protective equipment**

(Contd. on page 3)

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #12 Mycobacterium Medium

(Contd. of page 2)

· **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:**
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
· **Protection of hands:**

Protective gloves.

· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

9 Physical and chemical properties:

· **Form:** Liquid
· **Color:** Yellow tint
· **Odor:** Characteristic

	Value/Range	Unit	Method
· **Change in condition**			
· **Melting point/Melting range:**	Undetermined		
· **Boiling point/Boiling range:**	Undetermined		
· **Flash point:**	Not applicable		
· **Danger of explosion:** Product does not present an explosion hazard.			
· **Vapor pressure:**	Not applicable		
· **Density:**	Not determined		
· **Solubility in / Miscibility with** · **Water:**	Soluble		
· **pH-value:**	Not applicable		

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Dangerous reactions** No dangerous reactions known
· **Dangerous products of decomposition:**
No dangerous decomposition products known

11 Toxicological information

· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.

(Contd. on page 4)

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #12 Mycobacterium Medium

(Contd. of page 3)

· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
The substance is not subject to classification.
This product contains Carbon-14, a naturally occurring radioactive material. Each vial contains between 1-5 microcuries (0.035 - 0.185 mega becquerels) of radioactivity. The possession, use and distribution of this product may be subject to Local, Federal or International Regulations.

12 Ecological information:

· **Ecotoxical effects:**
· **Other information:**
The ecological effects have not been thoroughly investigated, but currently none have been identified.
· **General notes:** Generally not hazardous for water.

13 Disposal considerations

· **Product:**
· **Recommendation**
Smaller quantities can be disposed of with solid waste.
Must adhere to state and federal regulations.

· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to regulations found in 40 CFR 261
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **DOT regulations:**
· **Hazard class:** 7
· **Identification number:** UN2910
· **Proper shipping name (technical name):**
Radioactive material, excepted package
· **Remarks:** Transportation Index is 0 (zero)

· **Land transport ADR/RID (cross-border)**
· **ADR/RID class:** 7 Radioactive material
· **Item:** P.2
· **UN-Number:** 2910
· **Description of goods:** 2910 Radioactive material, excepted package

· **Maritime transport IMDG:**
· **IMDG Class:** 7
· **UN Number:** 2910
· **Marine pollutant:** No
· **Proper shipping name:** Radioactive material, excepted package

· **Air transport ICAO-TI and IATA-DGR:**
· **ICAO/IATA Class:** 7
· **UN/ID Number:** 2910

(Contd. on page 5)

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #12 Mycobacterium Medium

(Contd. of page 4)

· **Proper shipping name:** Radioactive material, excepted package

15 Regulations

· **Product related hazard informations:**
The substance is not subject to classification according to the sources of literature known to us.
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations pertaining to regulations on hazardous materials.

· **National regulations**
· **Additional classification according to Decree on Hazardous Materials:**
CERCLA: This product does not contain chemicals having a Reportable Quantity (RQ).
SARA 311/312: May be subject to reporting.
313: Not subject to reporting.
TSCA: This product is not regulated under TSCA.

· **Water hazard class:** Generally not hazardous for water.

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither Becton Dickinson or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

· **Department issuing MSDS:** Safety & Environment Department
· **Contact:** Technical Service Representative

USA

Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 02/01/2000 Reviewed on 12/17/1999

1 Identification of substance:

· **Product details:**

· **Trade name:** BACTEC #13 A Mycobacteria Medium

· **Article number:** 4402018

· **Manufacturer/Supplier:**
In the Continental United States call:
BD Biosciences
7 Loveton Circle
Sparks, MD 21152
Tel: (410)771-0100 or (800)638-8663

Outside the United States call:
Becton Dickinson France SA
Regulatory Compliance Dept.
BD Biosciences Europe
11 rue Aristide Berges BP 4
38800 Le Pont De Claix France
Tel: 33 4 76 68 36 36

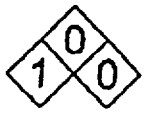
· **Information department:** Technical Services

2 Composition/Data on components:

· **Chemical characterization:**
CAS No. Description:
Carbon 14

3 Hazards identification

· **NFPA ratings (scale 0-4)**



Health = 1
Fire = 0
Reactivity = 0

4 First aid measures

· **General information** Immediately remove contaminated clothing.
· **After inhalation**
Supply fresh air; consult doctor in case of complaints.
· **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing** If symptoms persist consult doctor.

5 Fire fighting measures

· **Suitable extinguishing agents**
CO2, extinguishing powder or water spray. Fight larger fires with water or alcohol resistant foam.

(Contd. on page 2)

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #13 A Mycobacteria Medium

(Contd. of page 1)

· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

· **Person-related safety precautions:**
Wear protective equipment. Keep unprotected persons away.
· **Measures for environmental protection:** Wipe up with damp sponge or mop.
· **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
· **Additional information:** No dangerous substances are released.

7 Handling and storage

· **Handling**
· **Information for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
· **Information about protection against explosions and fires:**
No special measures required.

· **Storage**
· **Requirements to be met by storerooms and receptacles:**
No special requirements.
· **Information about storage in one common storage facility:**
Store away from oxidizing agents.
· **Further information about storage conditions:** None.
· **Class according to regulation on flammable liquids:** Void

8 Exposure controls and personal protection

· **Additional information about design of technical systems:**
No further data; see item 7.

Components with limit values that require monitoring at the workplace:
Not required.
· **Additional information:**
The lists that were valid during the creation were used as basis.

· **Personal protective equipment**
· **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:**
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
· **Protection of hands:**

Protective gloves.

· **Eye protection:** Safety glasses

(Contd. on page 3)

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #13 A Mycobacteria Medium

(Contd. of page 2)

· **Body protection:** Protective work clothing.

9 Physical and chemical properties:

· **Form:** Liquid
· **Color:** Yellow tint
· **Odor:** Characteristic

	Value/Range	Unit	Method
· **Change in condition**			
· **Melting point/Melting range:**	Undetermined		
· **Boiling point/Boiling range:**	Undetermined		
· **Flash point:**	Not applicable		
· **Danger of explosion:** Product does not present an explosion hazard.			
· **Vapor pressure:**	Not applicable		
· **Density:**	Not determined		
· **Solubility in / Miscibility with** · **Water:**	Soluble		
· **pH-value:**	Not applicable		

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Materials to be avoided:** Incompatible material: strong oxidizers.
· **Dangerous reactions** No dangerous reactions known
· **Dangerous products of decomposition:** No dangerous decomposition products known

11 Toxicological information

· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
The substance is not subject to classification.
This product contains Carbon-14, a naturally occurring radioactive material. Each vial contains between 1-5 microcuries (0.035 - 0.185 mega becquercls) of radioactivity. The possession, use and distribution of this product may be subject to Local, Federal or International Regulations.

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #13 A Mycobacteria Medium

12 Ecological information:

· **Ecotoxical effects:**
· **Other information:**
The ecological effects have not been thoroughly investigated, but currently none have been identified.
· **General notes:** Generally not hazardous for water.

13 Disposal considerations

· **Product:**
· **Recommendation**
Smaller quantities can be disposed of with solid waste.
Must adhere to state and federal regulations.

· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to regulations found in 40 CFR 261
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **DOT regulations:**
· **Hazard class:** 7
· **Identification number:** UN2910
· **Proper shipping name (technical name):**
Radioactive material, excepted package
· **Remarks:** Transportation Index is 0 (zero)

· **Land transport ADR/RID (cross-border)**
· **ADR/RID class:** 7 Radioactive material
· **Item:** P.2
· **UN-Number:** 2910
· **Description of goods:** 2910 Radioactive material, excepted package

· **Maritime transport IMDG:**
· **IMDG Class:** 7
· **UN Number:** 2910
· **Marine pollutant:** No
· **Proper shipping name:** Radioactive material, excepted package

· **Air transport ICAO-TI and IATA-DGR:**
· **ICAO/IATA Class:** 7
· **UN/ID Number:** 2910
· **Proper shipping name:** Radioactive material, excepted package

15 Regulations

· **Product related hazard informations:**
The substance is not subject to classification according to the sources of literature known to us.
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations pertaining to regulations on hazardous materials.

(Contd. on page 5)

BD

Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 02/01/2000 Reviewed on 12/17/1999

Trade name: BACTEC #13 A Mycobacteria Medium

(Contd. of page 4)

· **Hazard-determining components of labelling:** carbon 14

· **Safety phrases:**
13 Keep away from food, drink and animal feeding stuffs.
24/25 Avoid contact with skin and eyes.
27 Take off immediately all contaminated clothing.
28 After contact with skin, wash immediately with plenty of soap and water

· **National regulations**
· **Additional classification according to Decree on Hazardous Materials:**
CERCLA: This product does not contain chemicals having a Reportable Quantity (RQ).
SARA 311/312: May be subject to reporting.
313: Not subject to reporting.
TSCA: This product is not regulated under TSCA.

· **Water hazard class:** Generally not hazardous for water.

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither Becton Dickinson or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

· **Department issuing MSDS:** Safety & Environment Department
· **Contact:** Technical Service Representative

USA

The warranty is limited to the replacement of standard materials and parts on an exchange basis at the nearest facility or designated service location of Becton Dickinson Diagnostic Instrument Systems.

The BACTEC 460/TB 460 is designed to facilitate service by the use of easily removable modules. The module causing the malfunction is identified electronically. Replacement modules and other warranted parts are shipped F.O.B. the shipping point. There is no charge for replacement modules or labor. The user agrees to return the defective module and parts and to pay all transportation charges involved including that of the replacement module.

On site warranty service is available at per diem rates then in effect. Actual travel expenses incurred including reasonable food and lodging are also payable by the user. No charge will be made for defective parts replaced on an exchange basis.

Off site repairs shall also be made at no charge provided the instrument is carefully packed and returned by the user in boxes supplied by Becton Dickinson Diagnostic Instrument Systems. All freight and handling (both ways) shall be paid by the user. No replacement unit shall be furnished while off site repairs are made.

WARRANTY OUTSIDE CONTINENTAL UNITED STATES:

The purchase price includes spare modules and parts. Defective modules and parts shall be properly packaged and returned by the user for no charge replacement during the one year warranty period. All transportation charges (both ways) are payable by the user. Customs invoices should be marked "defective material returned for repair at no charge".

5.10 Radioactivity, Licensing and BACTEC

The rules for the use of the BACTEC system are relatively simple and straight-forward, mainly because of the small amount of radioactivity in each vial. The use of radioactive materials is controlled by the U.S. Nuclear Regulatory Commission (NRC) or, in certain states called "Agreement States", by an agency of the State government. State regulations are modeled on NRC regulations; the user must check the local regulations to verify that they do not differ from those of the NRC. The information below is provided as a guide to the BACTEC user; you are urged, however, to rely on the regulations for the actual requirements. The NRC regulations are spelled out in Title 10, Chapter 1 of the Code of Federal Regulations (usually abbreviated as 10 CFR).

5.10.1 What is Carbon-14?

Carbon-14 or ^{14}Carbon is a naturally occurring radioactive isotope of normal Carbon, ^{12}C. It is produced continuously by the cosmic rays from outer space that bombard our atmosphere, converting nitrogen atoms to carbon. There are a few other naturally occurring radioisotopes: uranium, thorium, radium and potassium-40 being the best known. There are huge quantities of these and they have been around for eons. This contrasts with the man-made radioisotopes, such as cobalt-60, cesium-137 and plutonium which did not exist in the environment until man put them there from nuclear explosions.

Carbon-14 is produced by cosmic rays at the rate of 30,000 Curies a year and the total world inventory is 280 million Curies. The quantity is constant since the rate of production equals the rate of decay by the 5,700 year half-life. It has been estimated that all nuclear weapons tested to date only added about 2% to the world inventory. (These values are in Curies, whereas the radioactivity in a BACTEC vial is in micro-curies (μCi) a million times smaller unit.)

This world inventory of carbon-14 is approximately 90% in deep oceans, 2% in the atmosphere and 8% in the surface waters and biosphere. Because the land area of the USA is almost 2% of that of earth, there are about 410,000 Curies of carbon-14 in our water and biosphere. This radioactive carbon is chemically indistinguishable from ordinary carbon. It becomes uniformly distributed throughout all biological material unless that material is so old that the carbon-14 has decayed away. Thus, there is carbon-14 in plants, trees, animals and paper but not in plastics and mineral oils.

We all have carbon-14 and a few other isotopes in our bodies. The most important of these are:

Isotope	Activity (μCi)	Half Life
Hydrogen-3 (Tritium)	0.7	12.3 years
Potassium-40	0.11	1.3 billion years
Carbon-14	0.08	5,700 years
Rubidium-87	0.02	47 billion years

So the total radioactivity in our body is about 1 μCi, i.e., about half a BACTEC vial with carbon-14 contributing almost 0.1 μCi. This amount of activity is constant throughout our life-time since the carbon is replenished from the carbon we eat. When we die, this stops and the carbon-14 decays, half of it disappearing in 5,700 years. Similarly, an average tree contains 10 to 20 μCi of ^{14}C. Archeologists measure the amount of carbon-14 in bones and wood they dig up and use this decay to estimate its age.

When ^{14}C atoms decay, they emit an electron which has an average energy of 50 kilovolts. This electron can not penetrate matter very easily. All are stopped by the glass walls and rubber caps of the BACTEC vials. These electrons have slightly more energy but are otherwise identical to those that produce the color picture in a TV set. This electron radiation is called beta-radiation and must not be confused with gamma-radiation which comes from reactors, cobalt-60 sources and very high voltage therapy equipment. Gamma-radiation is very penetrating; it is often thought of as being wavelike in character while beta-radiation is like little particles hitting the walls of the container. Gamma-radiation generally comes from man-made products and seldom occurs naturally.

Now suppose every hospital in the USA used BACTEC for blood cultures - how would this compare with the carbon-14 in our environment? If we assumed 9,000 hospitals doing an average of 5 blood cultures a day, they would use about 36 Curies in a year. Most of this activity is either buried in a landfill or stored in drums, but even if it were all spread throughout the land, it is less than one ten-thousandth of the carbon-14 radioactivity already there! So you see that the phrase "environmental pollution" is unrealistic when discussing carbon-14 and BACTEC since BACTEC uses the same isotope that is already universal in the environment (and in your body!). All garbage and trash contain carbon-14 (since garbage is about 30% carbon). In the normal, run-of-the-mill, everyday, "non-radioactive" hospital waste (containing plain old carbon in paper, vegetables, food, etc.) you dispose of 10 to 20 microcuries of "radioactive" carbon-14. So saying that no radioactive material can be put in garbage is talking about an impossible situation since it is already there.

(The facts presented are taken from three papers in the Journal of Health Physics: 30, 485 (1976), 32, 215 (1977), 34, 141 (1978).)

5.10.2 An "Exempt Quantity"

The regulations (10 CFR 30.18) state that a person who receives, possesses, uses, transfers, owns or acquires ^{14}C in quantities of 100 μCi or less is exempt from the licensing regulations in Parts 30-34 of 10 CFR. In other words, BACTEC vials can be used without a license and the user is not, then, a licensee. This is a very important fact for the rest of the 10 CFR regulations, in particular, 10 CFR 20 which deals with record keeping and waste disposal, all apply to "licensees" using "licensed material". Thus, they do not apply to the user of BACTEC vials who has no license. These small quantities of material are often referred to as "Exempt Quantities", though it is actually the user of them who is exempt - not the material itself.

5.10.3 Licensing in Non-Agreement States:

In this section we will describe the regulations of the USNRC that apply to users in States over which it has jurisdiction. At this time, these States are:

Alaska, Connecticut, District of Columbia, Delaware, Hawaii, Iowa, Illinois Indiana, Massachusetts, Maine, Michigan, Minnesota, Missouri, Montana, New Jersey, Ohio, Oklahoma, Pennsylvania, South Dakota, Utah, Virginia, Vermont, Wisconsin, West Virginia, Wyoming, Rhode Island.

These rules also apply to all hospitals operated by the U.S. Government (e.g., VA, Navy, etc.) in all States no matter whether Agreement or Non-Agreement.

The summary of the regulations below is correct to the best of our knowledge, When in doubt, we have checked with Mr. Nathan

Bassin, Chief of Radioisotope Licensing Branch, Nuclear Regulatory Commission (301/427-4228).

A. Use with no license (easiest method):

BACTEC may be used without any license whatsoever. This is because the quantity of carbon-14 in the vial is so small. The Regulations state in Part 30.8 (a):

> "Except as provided in paragraphs (c) and (d) of this section, any person is exempt for the requirements for a license set forth in Section 81 of the Act and from the regulations in Parts 30-34 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in paragraph 30.71, schedule B" (this is 100 μCi for carbon-14).

Thus, BACTEC vials can be used without a license and they are not subject to the rules for disposal in Part 20 since these rules only apply to people licensed under Parts 30-34 (from which the user is exempted). Hence, with no license, vials may be discarded in the laboratory trash.

To recapitulate,

1. No license is needed to use BACTEC and there is no limit to the quantity of vials you can possess. However, we at Becton Dickinson Diagnostic Instrument Systems are restricted by our NRC license so that we cannot send you more than 1000 μCi of carbon-14 in any one "transaction" which has been defined as a purchase order. If you want to take advantage of quantity discount on media, you must send us several purchase orders at one time. Suppose you would like to order thirty-six (36) gross of blood culture media to be shipped at a rate of three (3) gross a month for a year. Then, you must type one purchase order for three (3) gross media, but leave the purchase order number and delivery date blank. Make eleven copies and on each of the twelve purchase orders, put a new number and consecutive monthly dates. Put them in an envelope and send them to our Customer Service Department. You will get the price on thirty-six (36) gross of media and the monthly deliveries you want. This method of operation is suitable for the small hospital and it requires some extra paperwork.

2. The big advantage of not having a license is that there are no restrictions on the disposal of used vials. Autoclave them and discard with your other microbiology lab trash.

B. Use with a General License (preferred method):

The NRC has issued a General License in 10CFR 31.11 (a), 3 for the use of:

"Carbon-14, in units not exceeding 10 microcuries each for use in in-vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals."

In order to use this license, you must complete and file form NRC-483 (obtainable from Becton Dickinson Diagnostic Instrument Systems) which requires only your name, address, location of use and statement that you have the proper equipment (i.e., a BACTEC instrument) to use the vials. When you receive a validated copy of NRC-483 from the NRC with a registration number assigned, you must send us a copy. We can then accept a media order for any quantity of media on any delivery schedule.

The reason that the General License is the best way to use BACTEC is that it is very easy to get, it allows all the ordering advantages of a license yet it has none of the disadvantages or restrictions. This is because the regulations state in 10CFR 31.11 (f):

"Any person using byproduct material pursuant to the General License of paragraph (a) of this section is exempt from the requirements of Parts 19 and 20 of this chapter with respect to byproduct materials covered by that General License."

Part 19 covers notices, instructions and reports to workers. Part 20 is called "Standards for Protection Against Radiation" and deals with dose levels, caution signs, storage, reporting and waste disposal. Thus, with a General License you are not restricted by Part 20 and no special method is required to dispose of used BACTEC vials. You may, after autoclaving them, put them in the other trash from your microbiology lab. You do not need to pour the contents down the sink or put the bottles in drums to be carried away. In other words, you can use BACTEC vials exactly as though you did not have a license at all. However, as in all matters concerning the use of radioisotopes, we urge you to consult your Radiation Safety Officer and follow his instructions.

C. Use with license for human use of radioactive material:

If your hospital has a Specific License for human uses of radioactive material (as in a Nuclear Medicine department), you have already been issued a General License to use BACTEC and need take no further action. This is because Title 10, Code of Federal Regulations, Part 35.14 (c) states:

"Any licensee who is licensed pursuant to paragraph (a) of this section for one or more of the medical use groups in Part 35.100 also is authorized to use byproduct material under the General License in Part 31.11 of this chapter for the specified in-vitro uses without filing Form NRC-483 as required by Part 31.11 (b); Provided, That the licensee is subject to the other provisions of Part 31.11."

In other words, if your hospital license states that you are licensed to use Groups I (etc.) of Part 35.100 then you, de facto, possess a General License as described in Part (b) above and you do not need to apply for one by filing form NRC-843.

To recapitulate,

1. Your hospital license must be issued by the U.S. Nuclear Regulatory Commission and not by an Agreement State.

2. Your hospital license must use the exact words "Any byproduct material listed in Groups I (etc.) of Schedule A, Section 35.100 of 10 CFR 35."

3. If the above two conditions are satisfied, you may discard used BACTEC vials with other microbiology lab trash. You need do no paperwork for this to be permitted.

4. If your license does not satisfy condition (2), then read the next section.

D. Use with specific radioactive material license (most complicated method):

This type of license spells out the type of isotopes you can use, their physical form and the amount you can possess. You should not modify this license to include carbon-14 so as to use BACTEC. If you do, you probably will not be allowed to discard used bottles in laboratory trash but will have to use one of the disposal methods specified in 10 CFR Part 20.

What you should do is to complete form NRC-483 and send it back to the NRC. This is a very simple one-page form described in Part 31.11 of the Regulations. It may be obtained from the Technical Service department of Becton Dickinson Diagnostic Instrument Systems (telephone: 800/638-8656) or the Nuclear Regulatory Commission. When you get this license back, you may then discard the bottles in the trash.

There is no prohibition by the NRC on an institution having two or more licenses for different uses. So you can obtain a General License if you already have a Specific License.

Having two licenses does not lessen the power or control of your Radiation Safety Officer. In fact, it makes no difference to his operations - the second license is just a piece of paper to be filed away in a safe place.

To recapitulate,

1. Your hospital license must be issued by the U.S. Regulatory Commission and not by an Agreement State.

2. Your license will specify types of isotopes but contains no mention of Groups I, II, III, IV or V.

3. Obtain form NRC-483, fill it out and send to the NRC in Washington, DC.

4. When you get it back, you have a General License and may discard used BACTEC vials with the microbiology lab trash.

5.10.4 Licensing in Agreement States:

There are 26 Agreement States listed below - each of which has a set of regulations that, although based on those of the NRC, usually differ significantly from them. New York City has its own set which differ from those of New York State and the NRC.

Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Idaho, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Nebraska, Nevada, New Hampshire, New York State, New York City, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Washington.

Most states have established Exempt Quantities just like those of the NRC. Other states define exempt quantities but then severely limit the number of units that may be possessed so that the use for BACTEC vials is excluded. Again, some states have established a General License but others have restricted the quantity they may be possessed. We suggest that you read the foregoing sections on the various Non-Agreement Licenses so that you have this background information when you try to follow the rules of your state.

If your state has a General License for in-vitro clinical tests similar to NRC 10 CFR 31.11 (a), we suggest you use it since it is the simplest. Before getting this license, you can use the vials as Exempt Quantities if this is allowed. You must be guided by your Radiation Safety Officer and the responsible state officials.

To the best of our knowledge, the summary table on the next page lists the regulations of the Agreement States, references relevant sections and shows telephone number (1981 vintage) to contact. Since regulations are constantly changing, we cannot guarantee the accuracy of this information, although it has been checked recently. We suggest you call your state agency to

obtain a copy of the appropriate forms and the regulations; also inquire about recent changes that might affect you.

5.10.5 The Radiation Safety Officer:

The RSO is responsible for control of radioactive materials in your institution and should be contacted by you before the BACTEC is delivered so that he can assist you. He may have questions about the system or the licensing; please have him call Becton Dickinson Diagnostic Instrument Systems and we will be pleased to answer them.

5.10.6 Number of Vials Which May be Possessed:

With no license or with the NRC General License, there is no limit to the number of BACTEC vials or cases of vials which may be possess by the user at any one time or over any period of time. With a Specific License, there will be a limit specified in that document. Should this quantity not be large enough, it is usually easy to amend the license so as to increase it.

5.10.7 Handling of Vials:

There is no radiation emitted from the BACTEC vials; it is all contained within the vial. Exercise care in handling the glass vials to prevent breakage and damage to the seal. Do not drop vials; they are rugged but will break.

5.10.8 Broken Vials:

If a vial is accidentally broken, cover with paper towels and flood with disinfectant if necessary and then pick up any large pieces of glass and the metal seal with plastic-gloved hands, or better still, with tongs or tweezers to avoid being cut by broken glass. With disposable plastic gloves on your hands, use a pad of paper towels to mop up the liquid and to pick up the small pieces of glass. When all the free liquid and glass fragments have been removed, use more paper towels with a solution of detergent in hot water to clean the affected area. Rinse with clean water and dry. Put all pieces of glass, used paper towels and gloves into the same receptacle used for the disposal of used BACTEC vials.

The culture medium Package Insert, which is included in each case of vials, includes a reprint of the above procedure. This document has been approved by the NRC. In addition, the Product Evaluation Committee of the College of American Pathologists (CAP) has verified the following claim:

"Should a culture vial be broken causing liquid to spill onto a non-absorbing surface, e.g., an asbestos tile floor, the approved clean-up procedure takes less than 5 minutes and leaves no significant residue of surface radioactivity."

5.10.9 Disposal of Used Vials:

There are four methods that can be used to dispose of used vials. These are:

1. Discard with other micro lab trash.
2. Uncap vials and pour into sanitary sewer.
3. Incinerate vials.
4. Transfer to licensed waste disposal company.

We strongly recommend that, before disposal, all vials be autoclaved to destroy pathogenic organisms.

PRECAUTIONS:

As with any disposal procedure, draining BACTEC Media vials requires the practice of good laboratory hygiene. Practices such as:

* After autoclaving, allow vials to cool to room temperature before disposal.

* Wear rubber gloves (lightweight, disposal gloves are sufficient) when draining vials.

* No eating, drinking, or smoking while draining vials.

* Clean the disposal area well by wiping off bench top, sink walls, sink basin, Media Drainer, etc. with damp, disposable towel.

* Wash your hands prior to leaving laboratory or disposal area.

You must consult your RSO and obtain his concurrence before using any disposal method. In some institutions, a method may be forbidden even though allowed by the law. The RSO may make and enforce any regulation in his institution more stringent than the legal requirements.

1. Discard in the trash:

   This method is allowed when there is no license or when the General License is used. It is usually not allowed under a Specific License.

2. Pour into sanitary sewer:

   All NRC and Agreement States permit the contents of the vials to be poured into a sanitary sewer. The culture medium is considered to be diluted by the total volume the hospital discharges into the sewer. Thus, the final concentration is extremely low and well below permissible levels. Each institution may discard up to 1 Curie (500,000 BACTEC vials) a year in this manner.

   This is an inexpensive and easy way to dispose of used material provided that your RSO will agree to it. An excellent uncapping device is the Media Drainer (Catalog #00600) supplied by Becton Dickinson Diagnostic Instrument Systems. Another uncapping tool is sold by the West Company, Phoenixville, Pennsylvania 19460 as Model Ho-207. A cheaper, but less convenient one, is sold by the Pierce Chemical Company, P.O. Box 117, Rockford, Illinois 61105 as Model 13210.

3. Incineration:

The NRC and Agreement States permit incineration only when prior approval has been obtained. Consult the regulations for details. The main concern is that the concentration of radioactive gas at the outlet of the stack is below a level of 1×10^7 µCi/ml when averaged over a 24-hour period assuming daily disposal. To calculate the level you must obtain the air flow up the chimney from the hospital engineer. Suppose it is 1000 cubic feet a minute. Since 1 cubic foot = 2.83×10^4 ml, the flow is 2.83×10^7ml/minute or 1.70×10^9ml/hour. If the incinerator operates for 8 hours a day, the total volume of gas up the stack is 1.36×10^{10}ml/day. Suppose your hospital discards 200 BACTEC bottles a day. This is 400 µCi so the average concentration is:

$$\frac{400\ \mu Ci}{1.36 \times 10^{10} ml} = 0.29 \times 10^7\ \mu Ci/ml$$

This is about one third of the permissible level. You should include a calculation such as the above in any application to incinerate radioactive waste.

4. Transfer to Waste Disposal Company:

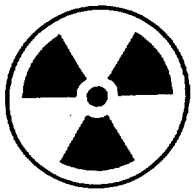
This involves placing the used vials in steel drums supplied by the disposal company. They will inspect them and then carry them away. It is usually possible to put about 1000 BACTEC vials into a 55 gallon drum. This method of disposal is the most expensive. The cost is minimized if you can fill 10 or more drums and then have the company pick them all up at one time. They will supply new drums and packing material. Should you have trouble locating a disposal company, ask your RSO for assistance or your local Becton Dickinson representative. He will know which other hospitals are using a waste disposal contractor.

5.10.10 Summary:

The rules for the use of the BACTEC system are relatively simple and straight-forward - mainly because of the small amount of radioactive material used in each vial. Common sense and the rules of good practice should be used in handling vials. Your Radiation Safety Officer can help in establishing these. Becton Dickinson Diagnostic Instrument Systems will also be pleased to help and answer questions on the licensing or use of the BACTEC system. Call us at 800/638-8656 and ask to speak to the Radiation Safety Officer.

BACTEC® TEST VIALS: CARBON-14

PP-045B
December 1990



- CAUTION: RADIOACTIVE MATERIAL — NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS
- THE CONTENTS OF THESE BACTEC TEST VIALS ARE EXEMPT FROM NRC OR AGREEMENT STATE LICENSING REQUIREMENTS.
- INTRODUCTION INTO FOODS, BEVERAGES, COSMETICS, DRUGS, MEDICINALS OR INTO PRODUCTS MANUFACTURED FOR COMMERCIAL DISTRIBUTION IS PROHIBITED.
- EXEMPT QUANTITIES SHOULD NOT BE COMBINED.
- THE CONTENTS OF THESE BACTEC TEST VIALS DO NOT EXCEED 10 MICROCURIES OF CARBON-14

The purpose of this Package Insert is to set forth appropriate radiation safety precautions and to suggest instructions for the handling, use, storage and disposal of the radioactive material.

HANDLING
Exercise care in handling the glass vials to prevent breakage and also damage to the seal. Do not drop the vials; they are rugged but will break.

USE
These vials are for use with BACTEC® instruments.

STORAGE
These vials should be stored in a cool, dry place (2° – 25°C). Note the "Use by" date on the outside of each package and use the oldest stock first. It is good practice to segregate radioactive materials by storage in a cabinet accessible only to authorized personnel. The cabinet should be labeled with the words "Caution: Radioactive Materials."

BROKEN VIALS
If a vial is accidentally broken, flood with disinfectant if necessary and then pick up any large pieces of glass and the metal seal with plastic-gloved hands, or better still, with tongs or tweezers to avoid being cut by broken glass. With disposable plastic gloves on your hands, use a pad of paper towels to mop up the liquid and to pick up the small pieces of glass. When all the free liquid and glass fragments have been removed, use more paper towels and a solution of detergent in hot water to clean the affected area. Rinse with clean water and dry. Put all pieces of glass, used paper towels and gloves into the same receptacle used for the disposal of used BACTEC vials.

DISPOSAL
Before disposal, all vials must be autoclaved to destroy pathogenic organisms. The contents of the vials may then be poured into a sanitary sewer while plenty of water is run to flush them away. Alternately, the vials may be placed in containers for disposal with other autoclaved laboratory waste material. Vials should be protected from breakage during this process.

NOTICE TO GENERAL LICENSEES
The radioactive material may be received, acquired, possessed and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

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December 1990

BACTEC® TESTFLÄSCHCHEN: KOHLENSTOFF-14

PP-045B
Dezember 1990

- VORSICHT, RADIOAKTIVE SUBSTANZ! NICHT ZUR INNEREN ODER ÄUSSEREN ANWENDUNG BEIM MENSCHEN ODER TIER BESTIMMT.
- TESTFLÄSCHCHEN ENTHALTEN WENIGER ALS 10 µCI KOHLENSTOFF-14.
- BEIMISCHUNG ZU SPEISEN, GETRÄNKEN, KOSMETIKA, MEDIKAMENTEN SOWIE ZU HANDELSWARE IST UNTERSAGT.

Der Zweck dieser Packungsbeilage ist, den Anwender mit angemessenen Strahlenschutzmaßnahmen vertraut zu machen und Hinweise für Behandlung, Gebrauch, Lagerung und Beseitigung von radioaktiven Substanzen zu geben.

BEHANDLUNG
Die Glasfläschchen sollten sorgfältig behandelt werden, um Glasbruch und Beschädigungen der Verschlußkappe zu verhindern. Die Fläschchen niemals fallen lassen: trotz ihrer Widerstandsfähigkeit können sie zerbrechen.

ANWENDUNGSBEREICH
Diese Fläschchen sind für die Verwendung mit BACTEC®-Geräten bestimmt.

LAGERUNG
Diese Fläschchen sollten kühl und trocken aufbewahrt werden (2 °C – 25 °C). Das Verfallsdatum auf jeder Packung beachten und die ältesten Bestände zuerst aufbrauchen. Es ist ratsam, radioaktive Substanzen von nicht-radioaktiven getrennt in einem besonderen Schrank aufzubewahren, der nur den dazu bevollmächtigten Mitarbeitern zugänglich ist. Der Schrank sollte folgendermaßen beschildert werden: „Vorsicht! Radioaktive Substanzen".

ZERBROCHENE FLÄSCHCHEN
Wenn ein Glasfläschchen versehentlich zerbrochen wird, Plastikhandschuhe überziehen und größere Glasscherben und den Metallverschluß aufsammeln. Noch ratsamer ist, Zangen oder Pinzetten zu verwenden, um Schnittverletzungen zu vermeiden. Danach mit von Wegwerf-Plastikhandschuhen geschützten Händen die Flüssigkeit mit einem aus Papierhandtüchern geformten Ballen aufnehmen und die kleineren Glasscherben aufsammeln. Die betroffene Umgegend mit zusätzlichen Papierhandtüchern und einer Reinigungslösung aus in heißem Wasser gelöstem Reinigungsmittel säubern, nachdem alle Flüssigkeit und Glassplitter entfernt worden sind. Alle Glasscherben, Papierhandtücher, Gummihandschuhe usw. in den gleichen Abfallbehälter werfen, der auch für gebrauchte BACTEC-Fläschchen verwendet wird.

ABFALLBESEITIGUNG
Vor der Beseitigung müssen alle Fläschchen autoklaviert werden, um pathogene Organismen abzutöten. Der radioaktive Abfall muß entsprechend den gesetzlichen Vorschriften entsorgt werden. Näheres teilt Ihnen Ihr Strahlenschutzbeauftragter mit.

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Dezember 1990

ATCH 2