Appendix N

Hazardous Materials Group Factual

Radioactive Materials Information

GUIDANT

FACSIMILE

DATE: August 19, 2002

TOTAL NUMBER OF PAGES (INCLUDING THIS PAGE): 3

TO: Jim Henderson

COMPANY: NTSB

FACSIMILE NUMBER: 202-314-6482

FROM: Jay Poston

TELEPHONE NUMBER: [redacted]

IF THIS TRANSMISSION IS NOT RECEIVED IN GOOD ORDER, PLEASE CALL JAY POSTON AT 713-218-4000 OR ADVISE BY FAX AT 713-218-4031.

000002

GUIDANT CORPORATION
VASCULAR INTERVENTION GROUP - TEXAS
1122 NORTH MAIN STREET, PEARLAND, TX 77581 USA
TEL 713-218-4000 FAX 713-218-4031

FedEx Express

Pg 1 of 1 Pgs

SHIPPING PAPER AND NOTIFICATION FOR LOADING OF DANGEROUS GOODS (PART U)

1

Shipper Regulatory Copy Retain 1 Year

☐ Yellow III Placard

☐ Dangerous When Wet Placard

Truck Placard Box Weight

Class / lbs

Proper Shipping Name	Class	UN#	Pkg Group	Sub Risks	Quantity & Type of Packing	Pkg Instr
Radioactive material, Type A package RQ PHOSPHORUS 32	7	UN2915			P-32 Solid SALT 1 Type A packages X 7.19000 GBq each XX TI0.0 Dimensions 25 X 46 X 63 cm each.	

Origin	Dest	Shipment Type (Delete Non-Applicable)	This Shipment Is Within The Limitations Prescribed For: (Delete Non-Applicable)	ULD/Comp# Bulk Truck Rt#	Remarks/Approvals/Authorizations

PEARLA TALLAHA

SB TLHA [redacted] Radioactive Passenger Aircraft [redacted]

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT. I HEREBY DECLARE THAT THE CONTENTS OF THIS CONSIGNMENT ARE FULLY AND ACCURATELY DESCRIBED ABOVE BY PROPER SHIPPING NAME AND ARE CLASSIFIED, PACKED, MARKED, LABELLED AND ARE ALL RESPECTS IN PROPER CONDITION FOR TRANSPORT BY AIR ACCORDING TO THE APPLICABLE INTERNATIONAL AND NATIONAL GOVERNMENTAL REGULATIONS.

Tracking #	24 hr. Emergency Telephone #
609669512022	8004249300

Shipper's Name and Address	Place/Date	Recipient's Name and Address
SHIPPING /713-218-4000 GUIDANT VI - PEARLAND 1122 N MAIN ST PEARLAND TX 77581 US	PEARLAND 07/25/2002	JERRY DOMICO TALLAHASSEE COMMUNITY HOSPITAL 2626 CAPITAL MEDICAL BLVD. DELIVER TO NUCLEAR MEDICINE TALLAHASSEE FL 32308 US

Signature BECKY WITT Title DISTRIBUTION CLERK

156800 M-0380U 06/01 SRC Typewritten Signature Acceptable

PICK LIST

DELIVERY NO.: 66262589
SHIPPED DATE: 07/25/2002
CUSTOMER NO.: 30695 2day BW 7-25-02
SHIPMENT METHOD: FED EX ~~PRIORITY OVERNIGHT~~
FREIGHT TERMS:
CONFIRMED BY: VICKIE SHARP 850-656-5169
SALES ORDER: 5116764

66262589

ORIGINAL PAGE 1/ ~~8~~ 1
BW 7-25-02

SHIPPED-FROM

GUIDANT
1122 N. Main St.
Pearland TX 77581

SHIP-TO

TALLAHASSEE COMMUNITY HOSPITAL
JERRY DOMICO - NUCLEAR MEDICINE
2626 CAPITAL MEDICAL BLVD
TALLAHASSEE FL 32308

Ref: 020723029/5116764
Dept:

Date: 26JUL02 SHIPPING $51.17
Wgt: 46 LBS SPECIAL $31.28
HANDLING $0.00
TOTAL $82.45

SERVICE: ** 2DAY **
TRACK: 6096 6851 2022

UPN PRODUCT NUMBER	PRODUCT DESCRIPTION LOT/SERIAL NUMBER	QUANTITY SHIPPED	PICK LOCATION	UoM	CUSTOMER PO
00802526281211	ACTIVE CART W/27MM WIRE, US			EA	123772
1008114-0C	28966820	1.00	NORM		
00802526267505	GDT P32-2 VECT S WIRE, ENG, USA			EA	123772
1008106-US	020723029	1.00	NORM		

NUMBER OF BOXES	TOTAL WEIGHT	PICKED BY	SHIPPED BY
1	46 lbs	[redacted]	[redacted]

Henderson James

From: Poston, Jay (John) (PEA) [redacted]
Sent: Friday, August 16, 2002 11:12 AM
To: Henderson James
Subject: RE: RAM Photos


GALILEO
Cartridge-Container Dr...


GALILEO
Cartridge-Container Dr...


GALILEO
Cartridge-Container Dr...


GALILEO
Cartridge-Container Dr...

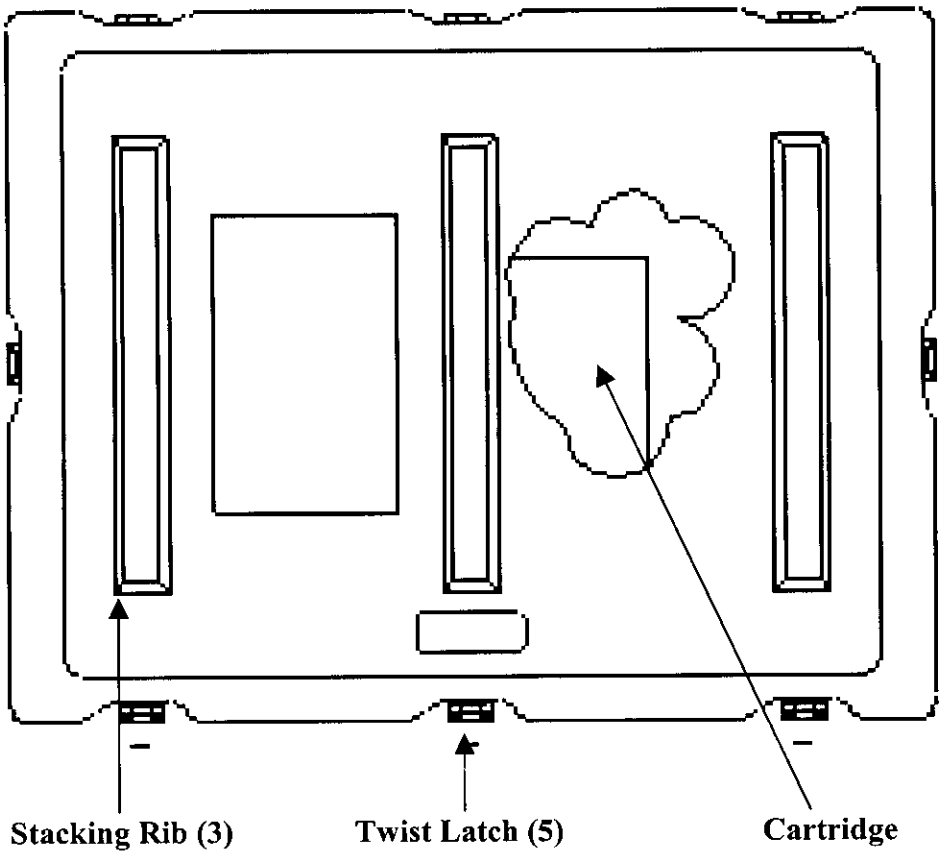

GALILEO
Cartridge-Container Dr...

The cartridge suitcase and its foam inserts are made of polyethylene. The cartridge exterior consists of a 6 mm thick aluminum bottom and a light gauge steel top. The cartridge interior contains a tungsten safe were the source wire is stored and shielded.

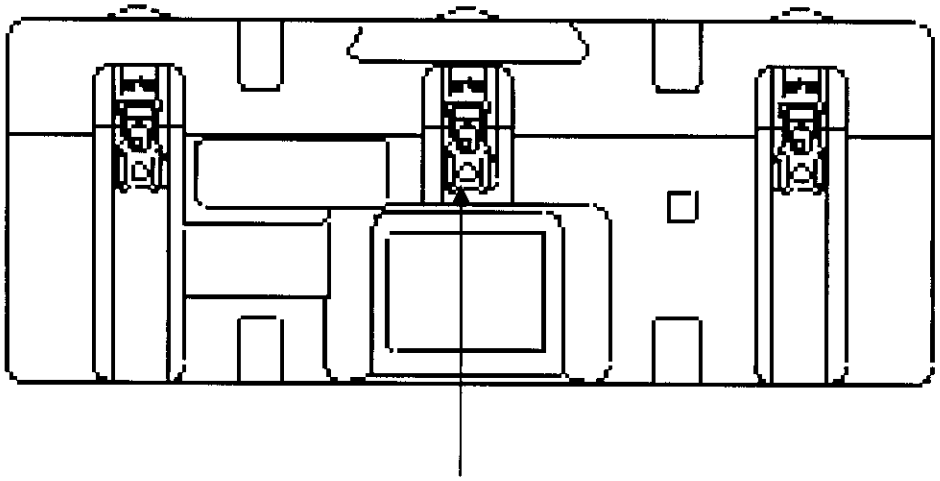
-----Original Message-----
From: Henderson James [redacted]
Sent: Friday, August 16, 2002 9:59 AM
To: Poston, Jay (John) (PEA)
Subject: RAM Photos

Jim H.

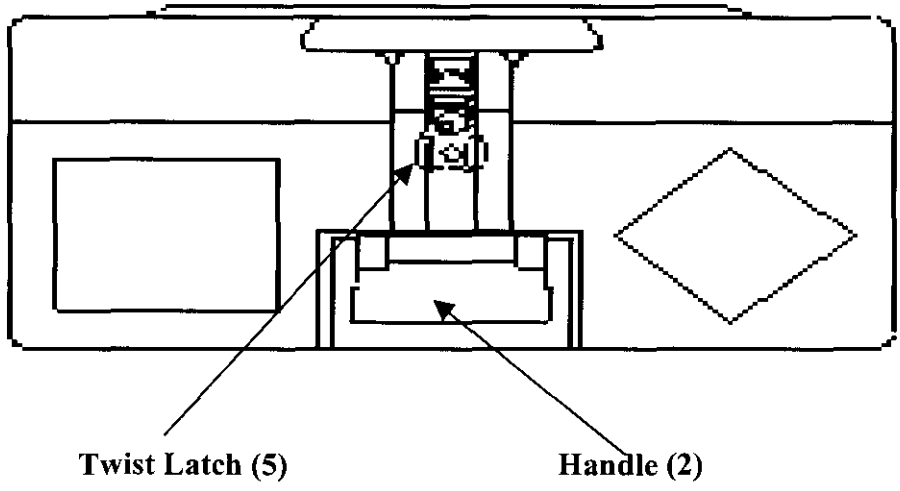
000005



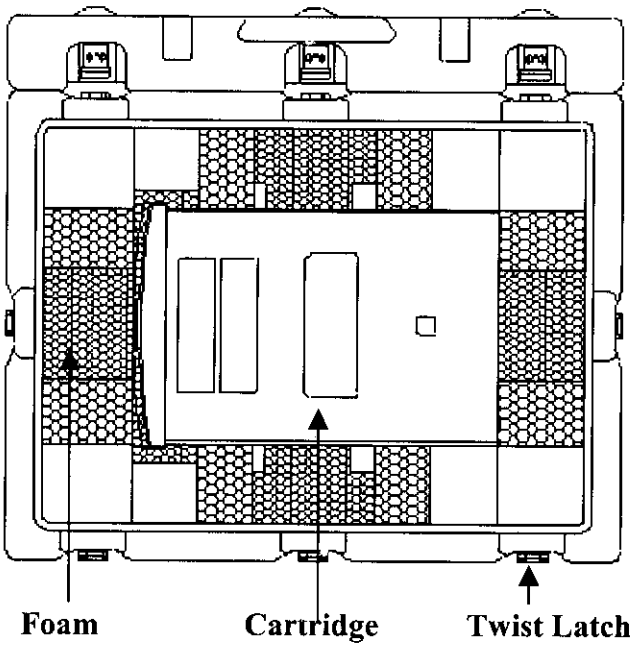
Top View of Closed Shipping Case



Front View of Closed Shipping Case



Side View of Closed Shipping Case



Top View of Open Shipping Case

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 PAGE 1 OF 6

DEVICE TYPE: Intravascular Brachytherapy (IVB) High Dose Rate Afterloader (HDR) Device

MODEL: GALILEO

MANUFACTURER /DISTRIBUTOR: Guidant Corporation
8934 Kirby Drive
Houston, TX 77054

SEALED SOURCE MODEL DESIGNATION: GDT P-32 Series

MANUFACTURER /DISTRIBUTOR: Guidant Corporation
8934 Kirby Drive
Houston, TX 77054

ISOTOPE: P-32 MAXIMUM ACTIVITY: 600 mCi

LEAK TEST FREQUENCY: N/A; length of service (8 weeks) precludes need.

PRINCIPAL USE: General Medical Use (V)

CUSTOM DEVICE: ____ YES __X__ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 PAGE 2 OF 6

DEVICE TYPE: Intravascular Brachytherapy (IVB) High Dose Rate Afterloader (HDR) Device

DESCRIPTION:

The GALILEO is a IVB HDR, computer controlled device developed to reduce the incidence of restenosis when used in conjunction with angioplasty by delivering a prescribed dose of beta radiation to an artery. The system consists of the Source Delivery Unit (SDU) which includes the cartridge, head and base, the centering catheter and the Physics Package (accessories for medical physics tests). These components formulate the system that delivers a source wire within a closed-end catheter to a patient's artery and returns it to a safely shielded position within a replaceable cartridge. Unlike a conventional HDR, the GALILEO is designed to be portable, **operated by a touch screen on the device**, and can be used in angiography laboratories or other rooms for medical physics checks without a requirement for supplemental shielding.

Source Delivery Unit (SDU):
The SDU is comprised of the cartridge, head, and base. The head has the central processing unit (CPU), motor drives, adjustable touch screen monitor with status indicator lights, stop button, manual retract wheel, cartridge receptacle, and treatment enable keyhole. The base has the height adjustment lever, adjustable neck, handle bar, power cord port, wheels with locking mechanisms, and emergency compartment which contains equipment necessary to handle an emergency situation. Access to the SDU is controlled via the System Key. The head and base are designed to remain on site for the useful life of the unit (10 years) without need for operator maintenance. A fully assembled unit is approximately 20" wide by 27" long with an adjustable height of 54" to 65".

The cartridge contains a tungsten safe, active wire, inactive wire, shutter mechanism, wire drive mechanism, operating software, catheter key port and eject button, part of the Emergency Retract System (ERS) for active wire retraction, and radiation sensor. After appropriate training, the entire cartridge may be removed and returned to the manufacturer for inspection, service, and source replacement. The source wire has been previously approved on TX-107-S-101-S with authorization to equip modified HDRs. Those sources are now acceptable for licensing purposes to include the GALILEO. To load the cartridge containing the source, the cartridge is inserted into the head and a spring loaded latch locks the unit precisely into place. The latch is secured with a Cartridge Key to restrict unauthorized use **or removal.** Interlock checks are performed as part of the quality assurance checks (QA) after each cartridge exchange **and/or when a problem may be suspected**.

Several devices and mechanisms are incorporated into the drive apparatus to prevent the source from remaining in the unshielded position except during patient treatment and while performing QA tests. One measure utilizes an inactive, non-radioactive wire of identical construction to traverse each catheter prior to the source wire being deployed to ascertain a clear and unimpeded pathway. Two sensors (infra-red and a diode for radiation) are utilized to ensure that the entire length of wire and the radiation source have returned to the tungsten shield. If any condition does occur whereby the source will not retract, redundant systems are integrated into the head and cartridge to assist in retrieving the source to the safe position. These include an emergency retract motor and manual retract wheel, both separate of the primary drive. A battery is also provided in the SDU base to power the ERS in the event of power loss or interrupt of service to the room of use. Treatment data is also retained in this eventuality.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 PAGE 3 OF 6

DEVICE TYPE: Intravascular Brachytherapy (IVB) High Dose Rate Afterloader (HDR) Device

DESCRIPTION CON'T:

Delivery Catheter:
The catheter is a multi-lumen, closed-end stretch of plastic tubing with a dedicated lumen used for placement and centering of the source wire. The catheter design precludes any direct patient contact with the source. The other lumens provide for inflating the balloon and inserting the guide wire used by the practitioner directing the catheter to the treatment area. Markers are imbedded into the distal end of each centering catheter to aid in the accurate placement of the source wire during treatment. On the proximal end of the catheter is a coded key connector that automatically identifies catheter characteristics. The CPU will then continuously monitor the catheter and retract the source should the coded key connector become disengaged.

Physics Package:
Accessories are provided with the GALILEO which enable appropriately trained personnel at the licensee's facility to verify the source activity and positioning. These QA checks should be performed **at intervals specified by the manufacturer and/or as per protocols accepted by nationally recognized bodies**. To perform these tasks, a Physics catheter is used to key the HDR in the Physics mode. Following this menu on the touch screen, a well chamber is connected for source calibration and an opaque plexiglass shielded fixture serves to enable a direct view of source positioning. This can be documented with radiochromic film. Although these tests are designed to be performed on a bench top under direct view, caution must be taken to ensure that the Physics catheter is securely connected to the well chamber or position verification fixture. Otherwise, the source wire could be extended to an open air position and potentially expose the operator to high beta radiation fields.

CONDITIONS OF NORMAL USE:

The GALILEO will be used in hospital based angiography suites in conjunction with angioplasty for the prevention of arterial restenosis. This unit, while non-sterile, will be used adjacent to sterile fields established during the therapeutic procedure. The GALILEO is authorized for clinical research and **general clinical use** under the auspices of a Food and Drug Administration (FDA)-approved Investigational Device Exemption (IDE) study or **Pre-market Approval (PMA)**. The unit may also be used for associated calibration and dosimetry work at authorized facilities in typical laboratory environments. Because of the short half-life, the source will have an expected useful life of approximately 60 days or 650 cycles, whichever comes first. When the GALILEO system is used as described in its Operating Manual, the source wire will be extended into the patient's body via a closed-end catheter for several minutes depending upon the source activity. The treatment time is controlled by system software to deliver the prescribed dose.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 PAGE 4 OF 6

DEVICE TYPE: Intravascular Brachytherapy (IVB) High Dose Rate Afterloader (HDR) Device

PROTOTYPE TESTING:

The GALILEO was developed, tested, and is manufactured in accordance with the FDA Quality System Requirements (QSR) (21 CFR, Part 820) as well as the ISO 9001 and ISO 13485 Standards. The device also complies with Underwriters Laboratories (UL) 2601-1/IEC 60601-1 standard for medical electrical equipment and the European Medical Device Directive 93/42/EEC. Test data is available on the GDT P-32 Series source under TX-107-S-101-S.

EXTERNAL RADIATION LEVELS:

For a maximum activity wire (600 mCi of P-32) in the cartridge, the exposure rate on contact (4.5 cm), 30 cm, and 100 cm is 1.2 mR/hr, 0.2 mR/hr, and background respectively. See TX-107-S-101-S for information on radiation levels of unshielded sources.

QUALITY ASSURANCE AND CONTROL:

Guidant maintains a quality assurance and control program which meets the requirements of FDA QSR as well as the ISO 9001 and ISO 13485 Standards. This program is designed to ensure that all components, whether manufactured internally or procured through a sub-contractor or supplier, will meet design specifications. Operational quality assurance procedures are incorporated into the Operator's Manual for verifying source strength and positioning accuracy. Devices and criteria specific to these procedures are available from the manufacturer.

LABELING:

The cartridge and shipping container are conspicuously labeled with the trifoil, isotope, and activity.

DIAGRAMS:

See attachments.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 PAGE 5 OF 6

DEVICE TYPE: Intravascular Brachytherapy (IVB) High Dose Rate Afterloader (HDR) Device

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. This device is authorized for: (1) human use under the auspices of an IDE or **PMA** issued by the FDA for clinical research **or general clinical use respectively**, (2) associated calibration measurements, or (3) medical research on animals. All possession and use requires appropriate licensing by the United States Nuclear Regulatory Commission (NRC) or an Agreement State.

2. Procedures for handling, storage, use, and cartridge exchange must be assessed by the licensing authority and should incorporate all requirements associated with the operation of an HDR evaluated for this use. Authorized users should be consistent with the FDA/IDE protocol and/**or** other licensing requirements for HDRs. Training in the proper use of GALILEO shall be provided by the manufacturer and include review of the Operator's Manual, the safe use of the device for routine and emergency conditions as well as cartridge exchange.

3. The sources will be leak tested prior to shipment to document that they are not leaking. Because of the short half life of the radionuclide and limited useful life of its dedicated cartridge, no further leak tests will be made prior to the user transferring the sealed source to the manufacturer.

4. The device is intended for **general clinical use in hospitals** or medical research institutions with appropriate regulatory (e.g., FDA, and NRC, or Agreement States) approval by specifying the device, source, and users on specific radioactive material licenses.

5. The licensee shall not cut, splice or alter the source wire in any manner except in emergency situations as stipulated in the Operator's Manual. Emergency procedures shall be prominently posted and/or immediately available to personnel whenever GALILEO is used either for patient treatment or during QA procedures.

6. The working life of a cartridge/source assembly shall be limited to sixty (60) days or 650 cycles, whichever comes first. The cartridge or GDT P-32 Series source may only be used in GALILEO or another HDR device for which an evaluation has been performed by the NRC, an Agreement State, or broad licensee with proper authority and in accordance with NRC Information Notice 99-24 or equivalent guidance from Agreement State authorities.

7. The GALILEO shall not be used for treatment until QA tests are performed in accordance with the manufacturers instructions **and/or protocols accepted by nationally recognized bodies**. Records should be required of the licensee to document each test and procedure performed.

8. Only manufacturer provided, single use, sterile catheters may be used with GALILEO for patient treatments. Quality assurance tests and measurements shall only be performed with the accessories provided or recommended by the manufacturer and in strict accordance with the procedures specified in the Operator's Manual **and/or protocols accepted by nationally recognized bodies**.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 PAGE 6 OF 6

DEVICE TYPE: Intravascular Brachytherapy (IVB) High Dose Rate Afterloader (HDR) Device

Con't

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

9. **IVB should only be performed at hospitals where emergency surgery capabilities exist should it become necessary to extract a source from a patient.**

10. **Radiation surveys with appropriate instrumentation must be performed before and after each procedure to verify that the source has returned to safe storage.**

11. **The GALILEO source should only be shipped when contained in the cartridge and packed in the approved shipping container.**

SAFETY ANALYSIS SUMMARY:

Based upon a review of the information and test data in the references cited below, the GALILEO is acceptable for licensing purposes for clinical investigations and **general clinical use** as stipulated by the FDA issued IDE or **PMA respectively**. We conclude that this device will be expected to maintain integrity during normal and accidental conditions that might occur during the anticipated use described in this document.

REFERENCES:

Amendment application dated January 31, 2000; Operator's Manual received June 16, 2000 and letters dated June 15, 2000, **August 10, 2001** and **Supplement #14 of October 22, 2001.**

ISSUING AGENCY: Texas Department of Health
Bureau of Radiation Control

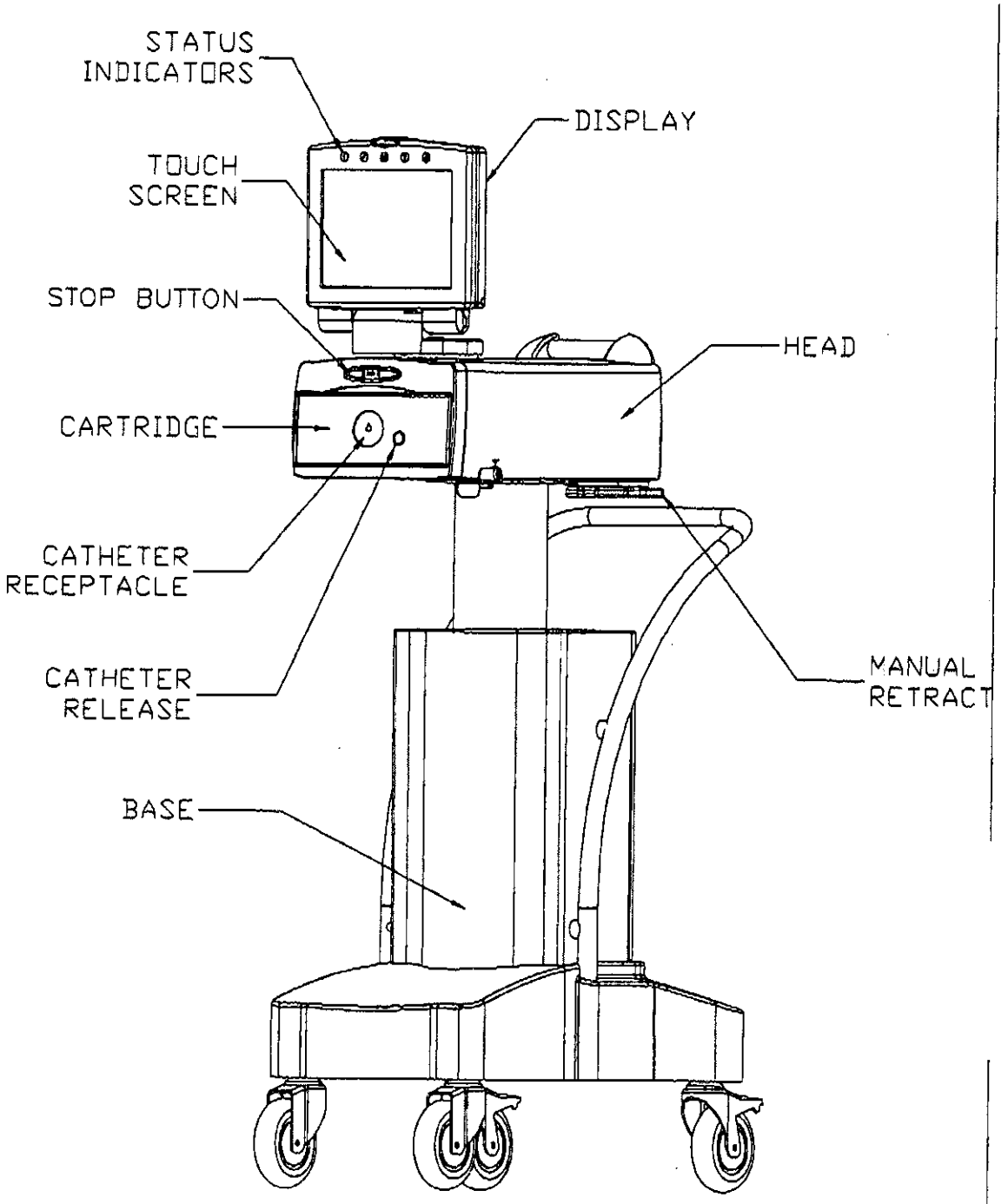
Date: November 14, 2001 Reviewer: [redacted]
D. Ray Tisha

Date: November 14, 2001 Concurrence: [redacted]
David M. Wood

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

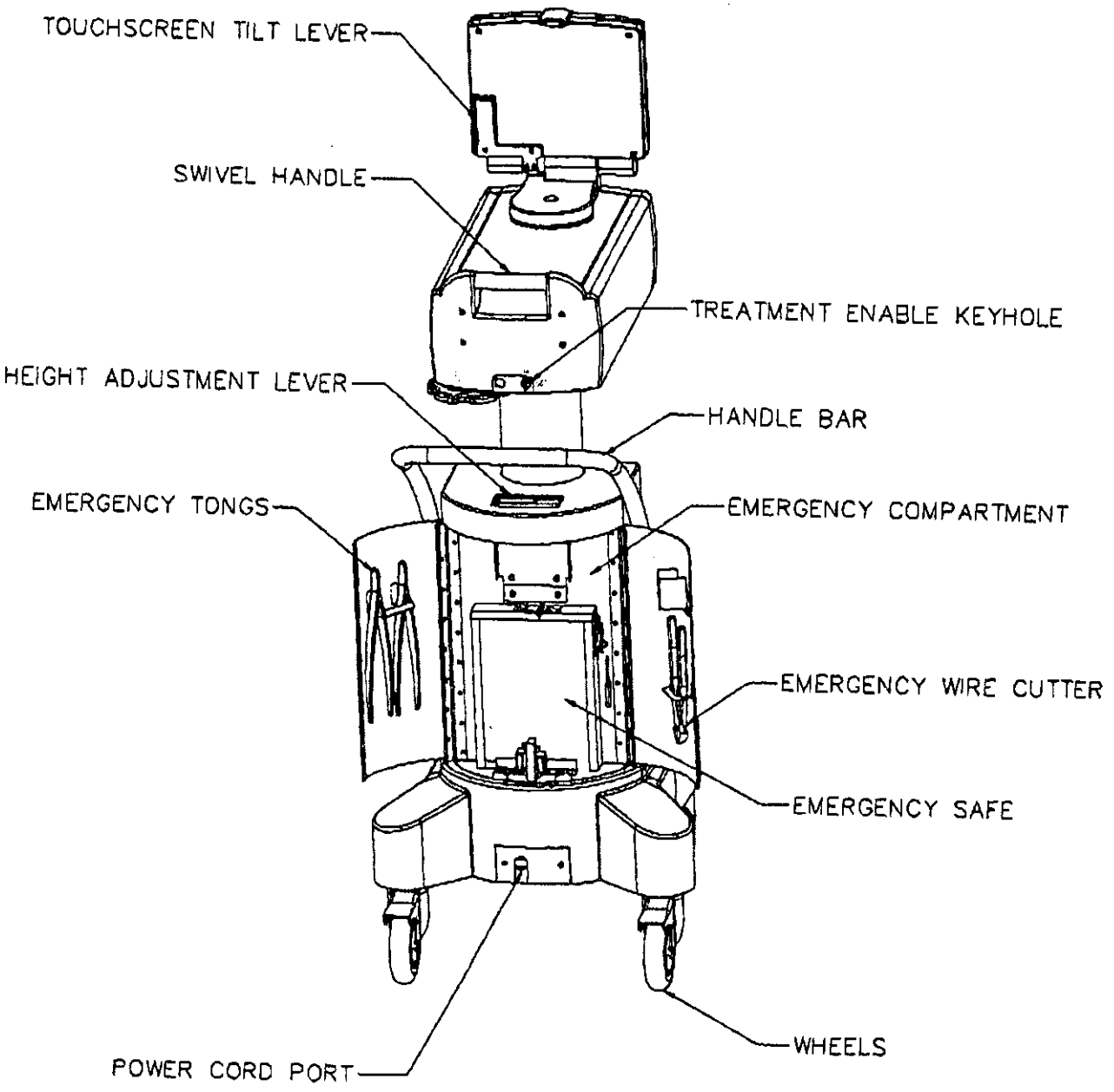
NO.: TX-1070-D-102-S DATE: November 14, 2001 ATTACHMENT 1 OF 3

DIAGRAMS:



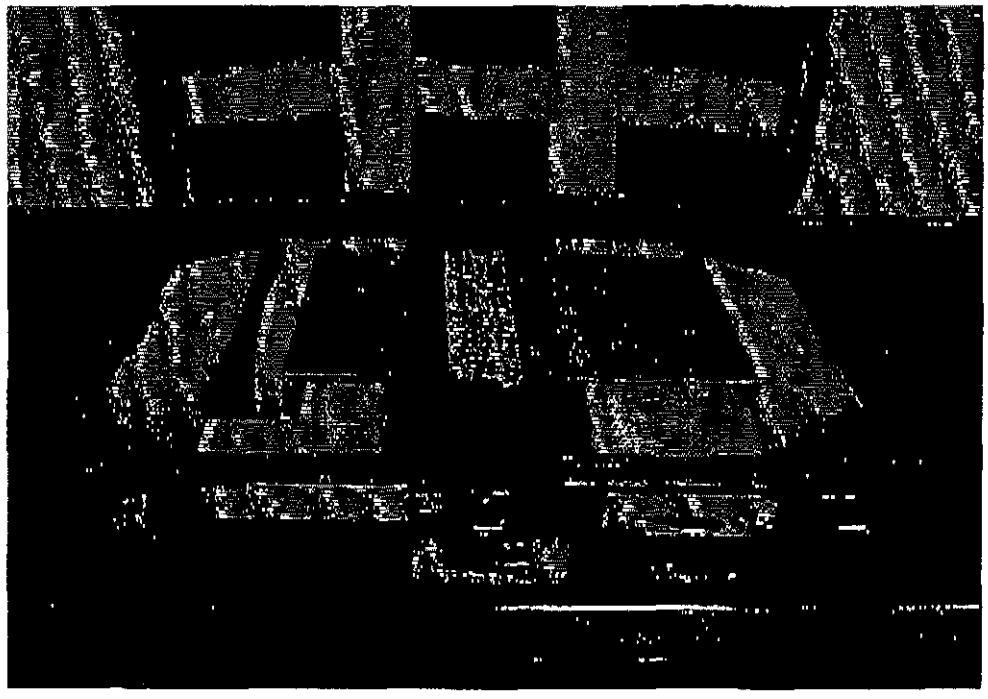
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 ATTACHMENT 2 OF 3

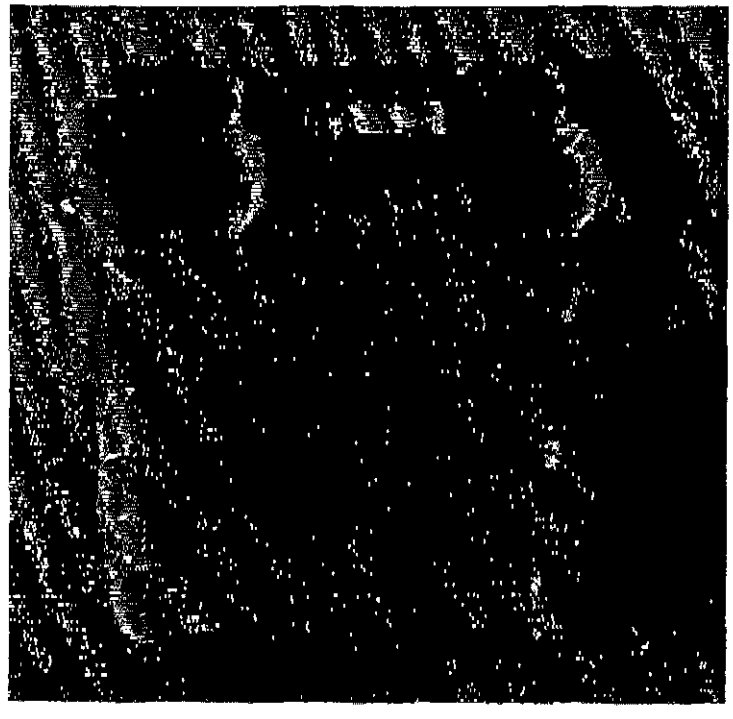


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: TX-1070-D-102-S DATE: November 14, 2001 ATTACHMENT 3 OF 3



SHIELDED SOURCE CARTRIDGE



SHIPPING CASE

Bristol-Myers Squibb Medical Imaging, Inc.
331 Treble Cove Road
North Billerica, Mass. 01862

facsimile transmittal

To:	Jim Henderson, NTSB, Wash. D.C.	**Fax:**	202-314-6482
From:	Skip Roy	**Date:**	08/19/02
Re:	Thallium Package Info.	**Pages:**	14
CC:			

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Notes:

The attached pages consist of the shipping documents for the two Thallium packages, the Thallium-201 MSDS, and excerpts from the Type A Package Certification Report describing the design of the inner and outer packaging.

I found out that we don't have an assembly drawing of the package so I thought the package certification description might help.

Contact me if you need any additional information.

- Skip Roy, Safety and Environmental Affairs

FedEx. Federal Express
Pg 1 of 1 Pgs

SHIPPING PAPER AND NOTIFICATION FOR LOADING OF DANGEROUS GOODS RADIOACTIVE MATERIALS (PART CR)

PRESS HARD - 10 PART FORM - USE BALL POINT PEN ONLY

Shipper's Copy
Remove at Origin

Yellow III Check Box for Placard

Proper Shipping Name	Class	UN#	Pkg. Group	Sub Risk	Quantity & Type of Packing	Pkg Instr
Radioactive material, Type A package	7	UN2915			1 X Type A Package	

Radionuclide (Product Code)	Phys & Chemical Form	Activity	Label Category	TI	Box Dimension (If Applicable)	Tracking #	ULD / Comp # Bulk Truck Rt #
YL201	LIQUID/SALT	5.686Bq	II YELLOW	0.3	26X25X 15CM	496511838029	

Origin	Dest	Shipment Type (Delete Non-Applicable)	This Shipment is Within The Limitations Prescribed For: (Delete Non-Applicable)	Remarks/Approvals/Authorizations
01 PMXA	XB VLDA	XXXXXXXXXXXXXXX XXXXXXXXXXXXXXX Radioactive	XXXXXXXXXXXXXXX XXXXXXXXXXXXXXX Passenger Aircraft	SO#388850 XX XX

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT. I HEREBY DECLARE THAT THE CONTENTS OF THIS CONSIGNMENT ARE FULLY AND ACCURATELY DESCRIBED ABOVE BY PROPER SHIPPING NAME AND ARE CLASSIFIED, PACKAGED, MARKED, LABELLED AND ARE IN ALL RESPECTS IN PROPER CONDITION FOR TRANSPORT BY AIR ACCORDING TO THE APPLICABLE INTERNATIONAL AND NATIONAL GOVERNMENTAL REGULATIONS

24 hr. Emergency/Telephone # (800)526-6549

Shipper's Name and Address	Place/Date	Recipient's Name and Address
Bristol-Myers Squibb Med. Img Inc. 331 Treble Cove Rd North Billerica, MA 01862	7/25/02	MEDISCAN, INC. 500 EAST ALDEN AVENUE VALDOSTA, GA 31602

Signature Donald Chartrand Title MANAGER

Typewritten Signature Acceptable

M-0390CR 2/01

FedEx. Federal Express
Pg 1 of 1 Pgs

SHIPPING PAPER AND NOTIFICATION FOR LOADING OF DANGEROUS GOODS RADIOACTIVE MATERIALS (PART CR)

PRESS HARD - 10 PART FORM - USE BALL POINT PEN ONLY

Shipper's Copy
Remove at Origin

Yellow III Check Box for Placard

Proper Shipping Name	Class	UN#	Pkg. Group	Sub Risk	Quantity & Type of Packing	Pkg Instr
Radioactive material, Type A package	7	UN2915			1 X Type A Package	

Radionuclide (Product Code)	Phys & Chemical Form	Activity	Label Category	TI	Box Dimension (If Applicable)	Tracking #	ULD / Comp # Bulk Truck Rt #
YL201	LIQUID/SALT	5.476Bq	II YELLOW	0.3	27X15X 14CM	496511838441	

Origin	Dest	Shipment Type (Delete Non-Applicable)	This Shipment is Within The Limitations Prescribed For: (Delete Non-Applicable)	Remarks/Approvals/Authorizations
01 PMXA	XB ABYA	XXXXXXXXXXXXXXX XXXXXXXXXXXXXXX Radioactive	XXXXXXXXXXXXXXX XXXXXXXXXXXXXXX Passenger Aircraft	SO#388808 XX XX

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT. I HEREBY DECLARE THAT THE CONTENTS OF THIS CONSIGNMENT ARE FULLY AND ACCURATELY DESCRIBED ABOVE BY PROPER SHIPPING NAME AND ARE CLASSIFIED, PACKAGED, MARKED, LABELLED AND ARE IN ALL RESPECTS IN PROPER CONDITION FOR TRANSPORT BY AIR ACCORDING TO THE APPLICABLE INTERNATIONAL AND NATIONAL GOVERNMENTAL REGULATIONS

24 hr. Emergency/Telephone # (800)526-6549

Shipper's Name and Address	Place/Date	Recipient's Name and Address
Bristol-Myers Squibb Med. Img Inc. 331 Treble Cove Rd North Billerica, MA 01862	7/25/02	NUMED, INC. 431 FLINT AVENUE ALBANY, GA 31701

Signature Donald Chartrand Title MANAGER

Typewritten Signature Acceptable

000020

M-0390CR 2/01

Bristol-Myers Squibb Company
Pharmaceutical Group
Material Safety Data Sheet

MSDS Number: DMP02483

Code : **CAS :** 55172-29-7 **Rev. Date :** 24-June-02

Status : 6 **Group :** Not Indexed

Manufacturer : Bristol-Myers Squibb Pharma

Trade Name : THALLOUS CHLORIDE TI 201 INJECTION

Synonyms : THALLIUMCHLORIDE; THALLIUM-201

Chemical Name : See Synonyms

OSHA Hazards : Not Indexed

Exposure Control Class / Exposure Guideline : Not Indexed

CERCLA/SARA : Not Indexed

Physical State : Not Indexed

Vapor Pressure : Not Indexed

DOT : Not Indexed **EPA HW :** Not Indexed

MSDS Image :

D0043.PDF

000021

D0043

THALLOUS CHLORIDE TI 201 INJECTION Revised 24-JUN-2002

CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification

CAS Number : 55172-29-7
Grade : CLINICAL

Tradenames and Synonyms

THALLIUM CHLORIDE
THALLIUM-201

Company Identification

MANUFACTURER/DISTRIBUTOR
Manufactured and distributed by:
Bristol-Myers Squibb Medical Imaging, Inc.,
331 Treble Cove Road, North Billerica, MA 01862

PHONE NUMBERS
Product Information : 1-800-343-7851
Medical Emergency : 1-800-343-7851

COMPOSITION/INFORMATION ON INGREDIENTS

Components

Material	CAS Number	%
THALLOUS CHLORIDE TI 201	55172-29-7	<0.1
INACTIVE INGREDIENTS		>99.9

HAZARDS IDENTIFICATION

Emergency Overview

CAUTION! RADIOACTIVE MATERIAL.
Colorless liquid.

May cause allergic reaction.
May cause skin and eye irritation.
May cause gastrointestinal, respiratory, and central nervous system effects.
May cause effects to the unborn child.
May be mutagenic.

No information is available for the environmental effects.

Potential Health Effects

Exposure to sufficient quantities of ionizing radiation has been known to cause harmful biological effects which include cancer, leukemia, and genetic and teratogenic effects. However, the health risks associated with radiation exposure are believed to involve levels of radiation that are much higher than the exposure levels permitted for occupational handling of radioactive materials.

Adverse reactions associated with the clinical administration of THALLOUS CHLORIDE TI 201 INJECTION include allergic reactions (characterized by cardiovascular, respiratory, and cutaneous symptoms), hypotension, pruritis, flushing, and skin rash. Other reported events include itching, nausea/vomiting, mild diarrhea, tremor, shortness of breath, chills, fever, conjunctivitis, sweating, and blurred vision.

Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

FIRST AID MEASURES

First Aid

INHALATION

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SKIN CONTACT

In case of contact, immediately wash skin with soap and water. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

INGESTION

If swallowed, immediately give 2 glasses of water and induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

THALLOUS CHLORIDE TI 201 INJECTION is a radiopharmaceutical suitable for intravenous administration by a qualified physician. No specific antidote for overexposure has been identified.

Allergic reactions including anaphylaxis have been reported following the administration of THALLOUS CHLORIDE TI 201. Anaphylaxis may be managed by appropriate administration of epinephrine and general life-support measures.

If ingested, and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious. An activated charcoal slurry may be used. To prepare, suspend 50 grams of activated charcoal in 400 mL of water in a plastic bottle and shake well. Orally administer 5 mL/kg, or 350 mL for an average adult.

FIRE FIGHTING MEASURES

Flammable Properties

Not a fire or explosion hazard.

Extinguishing Media

Water Spray, Foam, Dry Chemical, CO2. Use media appropriate for surrounding material.

Fire Fighting Instructions

Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

Spill Clean Up

Soak up with sawdust, sand, oil dry or other absorbent material.

Accidental Release Measures

If the product is received in a leaking condition or any loss or release of the radioactive contents occurs, notify your Radiation Safety Officer and follow spill control and waste management procedures for radioactive material spills.

HANDLING AND STORAGE

Handling (Personnel)

Do not breathe vapor or mist. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling. Wash contaminated clothing prior to reuse. Monitor radiation levels and minimize personnel exposure.

Storage

Store in accordance with Federal Regulations. Do not store or consume food, drink or tobacco in areas where they may become contaminated with this material. Store between 20-25 C (68-77 F).

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

CAUTION! RADIOACTIVE MATERIAL.

Handling time should be kept to a minimum, and appropriate shielding should be used. Handling devices such as syringe shields and tongs should be used.

Radioactive diagnostic agents must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide.

The vial containing the diagnostic agent should be kept within its container or within heavier shielding. Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation.

Personal Protective Equipment

Wear safety glasses with side shields. Wear full face protection when judged that the possibility exists for eye and face contact.

Wear an appropriate NIOSH approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

THALLOUS CHLORIDE TI 201 INJECTION

PEL (OSHA) :	None Established
TLV (ACGIH) :	None Established

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Boiling Point :	~100 C (~212 F) @ 1 mm Hg
Melting Point :	~0 C (~32 F)
Solubility in Water :	Soluble
pH :	4.5-6.5
Odor :	Odorless
Color :	Colorless.
Form :	Liquid.

THALLOUS CHLORIDE TI 201 INJECTION is supplied as a sterile, non-pyrogenic solution.

Physical Data: Radiation

Half-life : ~73.1 hour

Emissions : gamma rays and mercury x-rays

STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and storage conditions.

Incompatibility with Other Materials

None reasonably foreseeable.

Decomposition

Decomposition will not occur if handled and stored properly.

Polymerization

Polymerization will not occur.

TOXICOLOGICAL INFORMATION

Animal Data

Information on the adverse effects of this material in animal studies by the inhalation, dermal, ocular, or oral route(s) of exposure is not available.

The data presented are specific for Thallous Chloride. However, they may be applicable to the radioactive species THALLOUS CHLORIDE TI 201.

Oral Data
LD50: 24 mg/kg (mouse)

Intravenous Data
NOEL: 3.5 mg/kg (mouse)

Temporary cessation of breathing and decreased motor activity occurred in mice receiving 17 mg/kg.

Mutagenicity
Thallous Chloride was positive in one test.

Developmental Toxicity
Developmental abnormalities of the musculoskeletal system occurred in fetuses of rats dosed orally with 30 mg/kg of Thallous Chloride.

Carcinogenicity
No information available.
LD50 is the dose at which lethality occurred in 50% of the animals tested following oral exposure or exposure by injection.

NOEL is the No-Observed-Effect-Level

DISPOSAL CONSIDERATIONS

Waste Disposal

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations. Notify your site Radiation Safety Officer and follow waste management procedures for radioactive materials.

TRANSPORTATION INFORMATION

Shipping Information

DOT

Proper Shipping Name :	Radioactive material, n.o.s.
Hazard Class :	7
I.D. No. (UN/NA) :	UN2982
Packing Group :	N/A (Class 7 material is not assigned to packing groups)
Special Information :	The above applies to packages that are in categories I-White, II-Yellow, and III-Yellow.

OTHER INFORMATION

NFPA, NPCA-HMIS

NFPA Rating

Health :	0
Flammability :	0
Reactivity :	0

NPCA-HMIS Rating

Health :	0
Flammability :	0
Reactivity :	0

References

Information from research conducted or contracted by DuPont Pharmaceuticals Company.

Registry of Toxic Effects of Chemical Substances, 2/96.

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

MSDS Responsibility: Eileen Hayes 732-519-2385

# Indicates updated section.

This information is based upon technical information believed to be reliable. It is subject to revision as additional knowledge and experience is gained.

APPENDIX A

The pack being tested is a combination packaging comprising three (3) 10 ml liquid filled clear glass vials with red rubber friction fit plugs and metal crimp-on closures inner packagings.

Product information: Type A Radioactive material

INNER PACKAGING

Manufacturer	Not indicated
Style	Round glass vial
Nominal Capacity	10.0 ml
Overflow Capacity	14.6 ml
Tare Weight	19.1 gram
Size (mm,OD)	25 x 53
Material	Clear glass
Closure Type	Aluminum crimp-on closure (visual exam only); 21 x 7 (mm); 0.4 gram
Seal	Red rubber friction fit plug; 1.7 gram; 19 x 9.0 (mm)
Removal Torque	N/A
Handle	None
Gross Weight	30.9 grams
Count	Three 3/package
ID/Print	None

APPENDIX B

The pack being tested is combination packaging comprising a fibreboard regular slotted container 4G outer packaging.

OUTER PACKAGING

UN code	4G
Manufacturer	Interstate Container Corp, Lowell, MA
Style	Regular slotted container (International Box Code B1)
Size (mm, OD)	274 x 149 x 138
Weight	141.7 grams
Certification	200#; tests to 219 lbs/in² Burst Strength; 86.3(42.9/26.7/43.4) lbs/1000 ft² Combined Weight of Facings
Corrugations	Vertical "C" flute
Facings	Mottled white-kraft (visual exam only)
Mfr's Joint	Glued tab inside
Print	DuPont Pharma, Radioactive Materials N.O.S. UN2982, U.S.A. DOT-7A Type A Radioactive Material
Closure	72 mm clear pressure sensitive security plastic tape, one (1) piece on each top and bottom
ID	Single Pack 503201-1296

OUTER PACKAGING DETAIL(S)

1. Shield Container - 3 required
   Material - Lead (Visual exam only)
   Size (mm, OD) - 45 x 82 (including cover), 8 mm wall thickness
   Weight - 890 grams (including cover)

   The lead shield container with 40 x 11 (mm), 98 grams lead cover fitted with composite absorber, 25 x 3 (mm), 0.05 gram placed on the bottom foamed plastic pad and 43 x 11 (mm), 2.8 grams white plastic pull-off seal, is surrounded circumferentially with one (1) 140 x 50 (mm), 1.5 mm thickness glued foamed plastic strip and inserted into a plastic container (Detail #2) designed to provide secondary containment.

2. Cylindrical Shipping Container - 3 required
   Material - White polypropylene (as marked)
   Size (mm, OD) - 55 x 98 (including cover)
   Weight - 23.5 gram

   The container with 45 x 10 (mm), 0.7 gram placed on the bottom foamed plastic pad and 55 x 16 (mm), 5.0 grams white LDPE snap-on cover with breakaway tamper evident flange and glued atop folded paper strip for product information.

3. 2-Piece Box - 1 required
   Material - Expanded polystyrene (Visual exam only)
   Size (mm, OD) - 258 x 120 x 140 (including cover)
   Weight - 66 grams

   The box with fitted rectangular cover has three (3) 59 mm diameter cylindrical cavities to contain the inner packagings.

APPENDIX C

The following section details the compressive load *("SL")* applied in the stacking test.

Maximum gross weight of package, based on test level = GW (kg)
Gross weight of package, as tested = TW (kg)

GW = TW

GW = 3.1

GW = 3.1 kg

Stacking load equivalent to a 1.9 lb/in^2 (1336 kg/m^2) = SL (kg)
Outer packaging surface area projected vertically onto the top panel area = PH
Gross weight of package, based on the mark = GW (kg)

SL = 1336 kg/m^2 * PH

SL = 1336 kg/m^2 * 0.274 * 0.149

SL = 54.5 kg

SL = 55 kg