BIOHAZARDOUS MATERIAL TRANSPORTING PIG

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to Canadian Patent Application No. 2,955,469 filed on Jan. 20, 2017.

FIELD OF THE INVENTION

[0002] This invention relates to hazardous materials, for example radiopharmaceuticals. In particular this invention relates to a pig for storing, transporting and dispensing of liquid and capsules formulations of biohazardous products and substances in liquid and solid form, for example radiopharmaceuticals.

BACKGROUND OF THE INVENTION

[0003] The transportation of biohazardous materials and substances, for example radioactive materials or biological substances such as pathogens, presents a potentially dangerous situation and must be subject to strict controls.

[0004] For example, radioactive pharmaceutical products, commonly known as "radiopharmaceuticals," are prepared for patient injection, ingestion or other forms of administration in specially equipped and controlled facilities. Radiopharmaceuticals are well known for use as markers in nuclear medicine diagnostic procedures, and to treat certain diseases.

[0005] Unless properly shielded, such products become a radiation hazard for individuals handling the product. For example, radioiodine pills or capsules that can be used for treating certain pathologies such as thyroid diseases or in conjunction with a diagnostic procedure to diagnose certain types of illnesses, are stored before use in a container typically made of plastic, for example a polyethylene pill bottle. In the case of a liquid radiopharmaceutical the container is typically a glass vial. Neither of these containers have any radioactivity-shielding properties. Therefore the storage, transportation and dispensing of radiopharmaceuticals is carefully controlled by rules designed to regulate the handling of such materials in a manner that reduces the radiation hazard.

[0006] Each metered (for example assayed or calibrated) dose of the radiopharmaceutical product, for example in the case of a treatment for thyroid issues a radioiodine pill, or in the case of isotopes used in Nuclear Medicine (SPECT) and positron emission tomography (PET) diagnostic procedures a liquid, is placed by the manufacturer into the container to be shipped to a qualified facility for administration to a particular patient or patient category. At the radiopharmacy stock vials of different radiopharmaceuticals are dispensed as unit doses. This represents the first opportunity for hazardous exposure to the radioactive contents, and accordingly is effected at the manufacturer in a shielded booth or other enclosure, or under other radioactivity-shielded conditions.

[0007] The container containing the radiopharmaceutical must then be shipped to the destination hospital or clinic for administration to the patient. To effect this safely, the container is dropped into a radioactivity-shielding container commonly known as a "pig" for interim storage and delivery to the destination.

[0008] A conventional pig comprises a two-part vessel which is either formed from a radioactivity-shielding material, for example lead or tungsten, or has an exterior shell encasing a radiopharmaceutical container compartment that is lined with a radioactivity-shielding material such as lead or tungsten. A non-limiting example is described and illustrated in U.S. Pat. No. 6,586,758 issued Jul. 1, 2003 to Martin, which is incorporated herein by reference in its entirety.

[0009] When the pig is assembled, the radiopharmaceutical container compartment is sealed in order to contain the radiation and thus minimize human exposure to the radioactive contents of the radiopharmaceutical compartment. The compartment is sized to accommodate the radiopharmaceutical product, in the ingestible radioiodine example a pill or dissolving capsule, or in the case of a liquid of radiopharmaceutical a vial, syringe, ampule or other glass container. In each case the radiopharmaceutical compartment would be dimensioned accordingly.

[0010] Once the radiopharmaceutical container has been placed into the radiopharmaceutical compartment and the pig assembled, the pig is ready to be shipped to the patient's location. Because this part of the delivery process occurs entirely within the confines of the manufacturing plant, which is specifically designed and staffed so as to meet all regulatory guidelines and procedures, there is less chance of human exposure to the radioactive radiopharmaceutical product up to the point that the pill, capsule, vial, syringe or the like is sealed in the radiopharmaceutical container compartment of the pig. As is well known, the pig is designed to provide optimal shielding so as to reduce exposure during shipping. The transportation phase is a second opportunity for exposure to the radioactive contents of the radiopharmaceutical container, posing an occupational exposure opportunity for the driver/courier.

[0011] At the destination staff trained in handling radioactive substances, for example a nuclear medicine technologist or technician, opens the pig and then removes the closure from the radiopharmaceutical container to vent the container bottle. This is the third opportunity for exposure to the radioactive contents of the radiopharmaceutical container, in the presence of hospital or clinic staff. The technologist must transfer the radiopharmaceutical to a Dose Calibrator to assay (measure) the activity of the radiopharmaceutical, which must be within 10% of prescribed activity. After recording the assay, the technologist must retrieve container containing the radiopharmaceutical and return the radiopharmaceutical container to the pig's radiopharmaceutical container compartment, which is the third opportunity for exposure to radioactivity. The technologist then applies the lid to the pig for delivery to the patient.

[0012] The pig is opened in the patient's presence in order to gain access to the radiopharmaceutical container and remove the container closure for administration of the radiopharmaceutical product to the patient, providing a fourth opportunity for exposure to the radioactive contents of the radiopharmaceutical container. In this step exposure of radioactivity to the ambient environment is unavoidable in order to access the radiopharmaceutical product for administration to the patient, so great care must be taken to handle the unshielded radiopharmaceutical product using proper safety equipment and procedures.

[0013] However, the assaying process, and the venting of the container in the case of certain volatile radioactive