



PNRI REGULATORY BULLETIN No. 18-02

November 21, 2018

AUTHORIZATION TO TRANSPORT RADIOACTIVE MATERIALS

A. ADDRESSEES

All licensees who transport radioactive materials.

B. PURPOSE

This bulletin is issued to stipulate the necessary requirements in filling-out the attached “Application Form for the Authorization to Transport Radioactive Materials” when applying for authorization to transport to be covered by their radioactive material license, in compliance with PNRI Administrative Order No. 02 Series of 2017, which emphasized the importance of authorizing the transport of radioactive materials in the Philippines. This is a reiteration of the PNRI regulations requiring all PNRI licensees to ensure that any package containing radioactive material that is transported or shipped to and from an authorized location must comply with the requirements for the safe transport of radioactive materials. The said regulation specifically requires that the transport activities must be authorized in the PNRI radioactive material license. This bulletin sets the guidelines for the licensee who will be authorized to transport radioactive materials in the issued PNRI radioactive material license and if it would be inconvenient or difficult to secure the authority to transport from PNRI. It confirms that the licensee is the primary responsible for the safe transport of his licensed radioactive material in accordance with the regulations and the specific conditions of the license.

C. DESCRIPTION OF CIRCUMSTANCES

The following concerns on the transport of radioactive materials are received by the PNRI from the licensees:

1. Requesting assistance in seeking an exemption from MMDA Number Coding Scheme on the conveyance of radiopharmaceuticals, which are known to have short radioactive half-life and must be delivered to hospitals or clinics on time using a most reliable and effective means of transportation. Loss of “activity” of the radiolabelled product due to decay of the radionuclide during transport should be avoided in order to ensure its efficacy for the treatment of specific human disease.

2. Requesting for the reconsideration of the PNRI requirements to secure an Authority to Transport each time radiopharmaceuticals are transported to licensed end-users.
3. Suppliers of radiopharmaceuticals (dispensing) requesting to secure Permit to Transport ahead of time due to the urgency requirements of the Nuclear Medicine licensees.
4. Request of licensees to allow the monthly/yearly payment of the fees for the Permit to Transport to save human and financial resources. This is in connection with the government policy of cash basis payment of services rendered.
5. Sudden declaration of office suspension due to natural emergencies causes delay or non-issuance of Authority to Transport.

D. DISCUSSIONS

The PNRI has revised the Code of PNRI Regulations (CPR) Part 4, Regulations of the Safe Transport of Radioactive Material in the Philippines, and was published in the Official Gazette in Volume 113, No. 13 dated March 27, 2017. Section 8, Authorization to Transport Radioactive Material of the said regulation, states that, "No person shall transport or cause to transport radioactive material(s) by any mode - land, water or air, including transport which is incidental to the use of radioactive materials except in accordance with: (1) An authorization granted in the radioactive material license issued by the PNRI; or (2) Section 11, Permit to Transport issued to PNRI license holders not specifically authorized to transport radioactive material in their radioactive material license.

Furthermore, the PNRI published in the Official Gazette, PNRI Administrative Order No. 02 Series of 2017, New Schedule of Fees for Radioactive Material License with Extended Validity Period and Licenses Incorporating Authorization to Transport Radioactive Materials, (*amending for the Purpose Section 6 of the Code of PNRI Regulations (CPR) Part 22 Rev. 2. Section 2, New Schedule of Fees for Radioactive Material License incorporating Authorization to Transport*) provides the table for the fees for the transport of radioactive materials with varying validity of radioactive material license.

The PNRI regulations specify that holders of radioactive materials license are responsible for the protection of the health and safety of its workers and the public against the hazards of radiation in the performance of its licensed activities including the transport of radioactive materials. Movement or transport of radioactive materials from one location to another, if not done properly, poses some radiological risks. In transporting radioactive materials through public conveyances, the possibility of an accidental release, exposure, theft or loss of the radioactive materials should not be ignored. The effectiveness of a radiological emergency plan to cope with this occurrence lies in the availability of accurate and complete information about the material. This information should be addressed in the Consignors Declaration (CD) formerly called the Certificate of Transport (CT) which should be completed and issued by the licensee before any radioactive material leaves its premises for transport to another location.

Each Consignor's Declaration issued must include the following relevant information as stated in Section 10 of the revised CPR Part 4:

- (1) Date of issuance, and if appropriate, an expiration date;
- (2) Name, address, telephone/telefax number or e-mail address of the consignor (licensee) and PNRI license number;
- (3) Name and address of the consignor's RSO;
- (4) Information on the date of shipment and the expected date and time of arrival;
- (5) Description (name or symbol of each radionuclide, physical and chemical form and activity) of the radioactive material that will be transported;
- (6) Description of the package (category and dimension);
- (7) Measured dose rate on specific points of the package;
- (8) Transport index (for categories II-YELLOW and III-YELLOW only) and, if appropriate, any restrictions on the mode of transport and routing instructions;
- (9) Location, address and telephone number of the origin of the transport package;
- (10) Location, address and telephone number of the destination of the transport package;
- (11) Name, address and PNRI license number of the consignee/licensee;
- (12) Identification of the mode of transport. If transport is handled by a carrier/forwarder, indicate its name and other relevant information; and
- (13) Location, address and telephone number of the destination of the transport package;
- (14) Signature of consignor's RSO or consignor's representative responsible for the approval of the Consignor's Declaration; and
- (15) A declaration in the following terms or in terms having an equivalent meaning:

"I hereby declare that the content/s of this consignment is/are fully and accurately described above by the proper shipping name and classified, packaged, marked and labeled/placarded, and is/are, in all respects, in proper condition for the transport of **RADIOACTIVE MATERIALS** in accordance with PNRI regulations and applicable national governmental regulations."

Other responsibilities of the licensees are as follows:

- (1) Provisions for labeling and marking (e.g., radiation warning signs, symbols, stickers, identifications, etc.) in accordance with transport regulations;
- (2) Provisions for a locking or safety mechanism on the package;
- (3) Provisions for a written statement regarding actions, if any, that must be taken by the carrier and forwarder. The statement shall be in the vernacular appropriate for the carrier/forwarder or the parties concerned;
- (4) Submission of quarterly report to PNRI to include the number or frequency of transport activities performed by the licensee;

- (5) Keeping and maintenance of the CD(s) and quarterly report. Copies of CD issued should be made available upon demand during inspection by the **PNRI**.

Attached is a copy of the "Application Form for the Authorization to Transport Radioactive Materials" as a reference of the licensee in applying for the authorization to transport in the radioactive material license. For some clarification as to the compliance with the regulations and some particulars in this bulletin, the licensee should notify and communicate with the PNRI as it deems necessary.

E. REQUIRED ACTION

It is expected that all licensees will review this bulletin and assure that internal procedures for the transport of radioactive materials comply with the regulations. All licensees must ensure that the provisions of the applicable Parts and Sections of the Code of PNRI Regulations (CPR) Part 4 and the conditions of their authorization are satisfactorily addressed to prevent unnecessary disruption of authorized activities. The PNRI licensees are encouraged to uphold their commitment to protect human health and the environment from unnecessary exposure to radiation and to keep radiation exposure to the workers and the general public and releases of radioactivity to the environment below regulatory limits.

Please acknowledge receipt of this bulletin by mail or fax to the contact person.

CONTACT PERSON:

If you have any questions about this Bulletin, please contact the person listed below:

TEOFILO V. LEONIN, Jr.
Chief, Nuclear Regulatory Division

or

ALAN M. BORRAS
Head, Regulations and Standards Development Section/NRD

APPROVED:


CARLO A. ARCILLA, Ph. D.
Director

Date: December 18, 2018