MAHARASHTRA AUTHORITY FOR ADVANCE RULING

(constituted under section 96 of the Maharashtra Goods and Services Tax Act, 2017)

BEFORE THE BENCH OF

(1) Shri B. V. Borhade, Joint Commissioner of State Tax
(2) Shri Pankaj Kumar, Joint Commissioner of Central Tax

GSTIN Number, if any/ User-id		27AADCN5392G1Z9
Legal Name of Applicant		NUECLEAR HEALTHCARE LIMITED
Registered Address/Address provided while obtaining user id		PLOT NO D/37-1, TTC MIDC, TURBHE, NAVI MUMBAI – 400703
Application details		GST-ARA, Application No.02 Dated 28.11.2017
Concerned officer		AC, Division-III, Belapur
Nature of activity(s) (proposed / present) in respect of which advance ruling sought		
A	Category	Manufacturing
B	Description (in brief)	Applicant is engaged in the business of manufacturing of fludeoxyglucose F 18, also commonly called FDG, radiopharmaceutical used in the medical imaging modality positron emission tomography (PET).
Issue/s on which advance ruling required		(i) classification of goods and/or services or both
Question(s) on which advance ruling is required		1) Whether the product 'Fludeoxyglucose' or 'FDG' can be classifiable under Chapter 3006 3000 of the Central Excise Tariff Act, 1985 ? 2) Whether chemicals used as phramaceuticals that are inorganic or/ and of organic nature shall merit classification only under Chapter 28 & 29 and not under Chapter 30 which has been specifically carved out for chemical pharmaceuticals by makers of law ?

PROCEEDINGS

(under section 98 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017)

NO.GST-ARA-02/2017/B- 02 **Mumbai, dt. 21/02/2018**

The present application has been filed under section 97 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017 [hereinafter referred to as "the CGST Act and MGST Act"] by Nueclear Healthcare Limited, the applicant, seeking an advance ruling in respect of the following questions :

- *Whether the product 'Fludeoxyglucose' or 'FDG' can be classifiable under Chapter 3006 3000 of the Central Excise Tariff Act, 1985 ?*
- *Whether chemicals used as pharmaceuticals that are inorganic or/ and of organic nature shall merit classification only under Chapter 28 & 29 and not under Chapter 30 which has been specifically carved out for chemical pharmaceuticals by makers of law ?*

At the outset, we would like to make it clear that the provisions of both the CGST Act and the MGST Act are the same except for certain provisions. Therefore, unless a mention is specifically made to such dissimilar provisions, a reference to the CGST Act would also mean a reference to the same provision under the MGST Act. Further to the earlier, henceforth for the purposes of this Advance Ruling, a reference to such a similar provision under the CGST Act / MGST Act would be mentioned as being under the "GST Act".

02. FACTS AND CONTENTION – AS PER THE APPLICANT

The submissions, as reproduced verbatim, could be seen thus-

"ANNEXURE 1 – STATEMENT OF FACTS

(1) The Applicant is a company engaged in the business of manufacturing of fludeoxyglucose F 18, also commonly called FDG, radiopharmaceutical used in the medical imaging modality positron emission tomography (PET). The Applicant has secured renewal of the license to operate a medical cyclotron from Atomic Energy Regulatory Board (AERB) for plant located at Plot No D/37-1, TTC MIDC, Turbhe, Navi Mumbai – 400703 (**Exhibit "A"**).

(2) The Applicant currently operates the medical cyclotron, as per prescribed regulations of the Atomic Energy Act, 1962, the Atomic Energy (Radiation Protection) Rules, 2004, the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987 and all applicable safety codes, guides on safety and security issued by AERB for the manufacturing/ handling of FDG and directives/ other applicable regulatory documents issued y AERB from time to time.

(3) The Applicant conducts series of prescribed scientific processes at the medical cyclotron to manufacture a radiopharmaceutical called as Fludeoxyglucose (^{18}F), or fludeoxyglucose F 18, also commonly called fluorodeoxyglucose and abbreviated [^{18}F]FDG, ^{18}F-FDG or FDG (hereinafter referred to as "^{18}F-FDG" or "FDG"). The details of the product FDG, the synthesis/ manufacturing procedure, mechanism of action, metabolic end-products, and metabolic rate, distribution, production and application thereof is mentioned in a separate note as sourced from WIKIPEDIA (**Exhibit "B"**). The Applicant currently manufactures only FDG and no other product at the medical cyclotron facility.

(4) The Applicant currently manufactures and dispatches the labelled ^{18}F-FDG compound in measured doses of ordered mCi (*unit of measurement*) into individual sterile vials for administering to the scheduled cancer patients at the respective PET scanning facilities from the medical cyclotron, to the institution managing the PET scanning facilities, authorised by AERB like Hiranandani Hospital, Lilavati Hospital, P D Hinduja Hospital, Aditya Birla Memorial Hospital, Breach Candy Hospital, HCG, Appollo Hospital, etc. and also to the PET scanning facilities, authorised by AERB and operated by the Applicant, by adhering to the stipulated safe transport regulation, in specialised shielded tungsten containers.

(5) The Applicant has obtained registration under the erstwhile provisions of Central Excise Act, Maharashtra Value Added Tax Act and the Central Sales Tax Act, as assesse/ dealer for the nature of business as 'manufacturer' and has paid the applicable duties/ taxes. The Applicant has been informed during the course of the excise proceedings that the product FDG is a keen to Chapter Heading 2844 4000 and the Applicant has accordingly discharged the duty payable as per the provisions of the Central Excise Act. The Applicant has obtained registration under Goods and Service Tax Act, on transition, with registration number as 27AADCN5392G1Z9 and continued to discharge the GST liabilities under the Chapter Heading 2844 4000 till date.

(6) There are currently about 15-20 medical Cyclotrons operating in various government and private establishments and closest one of them being operated from Radiation Medicine Centre, B.A.R.C., Tata Memorial Centre Annexe, Mumbai which is operated by the Board of Radiation and Isotope Technology, Department of Atomic Energy, Government of India. The Applicant has come across legal infirmity or mis-appreciation of facts or wrong invocation of statutory provisions or mis-interpretation of law or non-standard approach across the manufacturers for classification of same product FDG under the relevant chapter heading at these various government and private establishments."

ANNEXURE 2 – APPLICANT'S VIEW POINT AND SUBMISSIONS ON ISSUES ON WHICH THE ADVANCE RULING IS SOUGHT

1. "The classification informed by the department and as followed by some of the manufacturers of FDG, under Chapter Sub-Heading 2844 of the Central Excise Tariff, with regard to medicament and pharmaceutical product manufactured by the applicant, suffer with certain anomalies, which has crept in due to non-appreciation of vital facts.
2. The classification informed by the department and as followed by some of the manufacturers of FDG appears to have presided over on the basis of following precincts under Chapter Sub-Heading 2844, which *interalia* states that :
   - Chapter Note 6 - *Heading 2844 applies only to: (a) technetium (atomic No. 43), promethium (atomic No. 61), Polonium (atomic No. 84) and all elements with an atomic number greater than 84; (b) natural or artificial radioactive isotopes (including those of the precious metals or of the base metals of Sections XIV and XV), whether or not mixed together; (c) compounds, inorganic or organic, of these elements or isotopes, whether or not chemically defined, whether or not mixed together; (d) alloys, dispersions (including cermets), ceramic products and mixtures containing these elements or isotopes or inorganic or organic compounds thereof and having a specific radioactivity exceeding 74 Bq/g (0.002 micro µci/g); (e) spent (irradiated) fuel elements (cartridges) of nuclear reactors; (f) radioactive residues whether or not usable. The term "isotopes", for the purposes of this Note and of the wording of headings 2844 and 2845, refers to: (i) individual nuclides, excluding, however, those existing in nature in the monoisotopic state; (ii) mixtures of isotopes of one and the same element, enriched in one or several of the said isotopes, that is, elements of which the natural isotopic composition has been artificially modified.*;
   - Section Note 1A of Section VI - *Goods (other than radioactive ores) answering to a description in heading 2844 or 2845 are to be classified in those headings and in no other heading of this Schedule*; and
   - the explanatory note to Chapter subheading 2844 of Harmonized Commodity Description and coding system, Vol-I, page no. VI-2844-1 and VI-2844-2 - *the Chapter heading 2844 and 2545 covers not only isotopes in their pure state but also chemical elements whose natural isotopic composition has been artificially modified by enriching the elements in some of their isotopes or by converting through a nuclear reaction, some isotopes into other, artificial isotopes. Radioisotopes of these same elements obtained artificially (e.g. Be 10, f 18, Al 29, P 32, Mn 54) are however to be considered as isotopes*;
3. The classification of FDG on these precincts and further conclusion then that all radiopharmaceutical products (whether ready to use diagnostic or/and therapeutic) as referred to in 2 above and their likes are to be classified under Chapter Subheading 2844 of the Central Excise Tariff Act, 1985, suffers with legal infirmity, mis-appreciation of facts and wrong invocation of statutory provisions. Here, the Applicant would like to bring to your kind notice, the following clarificatory provisions of the Central Excise Statute read with the relevant portions of HSN Explanatory Notes and legal pronouncements by Judiciary, if any, in support of our averment that FDG are pharmaceuticals and shall merit classification under Chapter 30, more precisely under Chapter Sub-headings 3006 3000. To substantiate the above, the Applicant further submit that :-
   3.1 It is an established fact that chemicals used as pharmaceuticals can be of inorganic or/and of organic nature. It does not mean therefore that they all shall merit classification under Chapter 28 & 29 only and not under Chapter 30, which has been specifically carved out for chemical pharmaceuticals, by makers of the law.
   Our above averment gets legal sanctity, support and substantiation by the following :-
   3.1 (i) attention is solicited towards Note 2 of section VI of CETA, 1985, which *interalia* mentions that **"Subject to Note 1 above, goods classifiable in heading 3004, 3005, 3006, 3212, 3303, 3304, 3305, 3306, 3307, 3506, 3707 or 3808 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of this Schedule."**.
   3.1 (ii) further, as per Note 3(a) (2) of Chapter 30, **"for the purpose of headings 3003 and 3004 and of Note 4(d) to this Chapter, all goods of Chapter 28 or 29; are to be treated as unmixed products".**
   This clearly implies that those chemical products, which qualify to be classified under Chapter 30 (Heading 3004 etc.) are not required to be classified as chemical under Chapter 28 or 29.

3.2 The Applicant further say that FDG having pharmaceutical use shall merit classification under Chapter 30 due to the following :-

3.2 (i) as per Note 4(d) of Chapter 30 - Heading 3006 applies only to the following, which are to be classified in that heading and in no other heading of this Schedule

3.2 (iii) to support the fact that FDG are put up in measured doses and are supplied in packings for therapeutic or prophylactic use, the Applicant hereby submits the following documents for your kind perusal.

- **"Exhibit C"** - I/II/III indicate sample copies of our invoices indicating that sale of such pharmaceutical products are made to hospitals or such institutions for medicinal purpose.

4 The Applicant further say that the FDG shall be reclassified and shall attract classification as 3006 3000 (diagnostic reagents designed to be administered to the patients). This is because –

- the product meet the requirement as stated at 3.2 (i) & 3.2(ii) above for being classified under Chapter 30.
- the diagnostic radiopharmaceuticals merit classification under Chapter Sub-heading 3006 3000 because -

(a) they are diagnostic reagents designed to be administered to the patient, being unmixed products put up in measured doses or products consisting of two or more ingredients which have been mixed together for such uses, as per para 3(d) of notes to Chapter 30.

(b) they also meet the criteria of HSN [Page. 473, explanation 30.06(5)], which states that "the diagnostic reagents (including microbial diagnostic reagents) covered by the heading are those administered by Ingestion, Injection, etc.
Diagnostic reagents not designed to be administered to the patient (e.g. those for carrying out tests on blood. Urine etc., samples taken from a patient or for use as laboratory reagents) are excluded; they fall in the headings appropriate to the materials of which they are made (e.g. Chapter 28, Chapter 29 or heading 30.02 or 38.22).

(c) the FDG (F-18 based injectable products) are meant for organ/tissue imaging. The product is also administered in measured doses to the patients and are used for diagnosis in oncology, neurology and cardiology. Therefore the product need to be classified under CETSH 3006 3000 (Technical literature for FDG is attached as Exhibit B).

5. The Applicant further say that the interpretation of the Applicant also coincides with the interpretation of the Board of Radiation and Isotope Technology (BRIT), Department of Atomic Energy, Government of India who is operating the oldest medical cyclotron in the country at Radiation Medicine Centre, B.A.R.C., Tata Memorial Centre Annexe, Mumbai. The Director of Bhabha Atomic Research Centre is designated chairman of BRIT and Joint Secretary (I&M), Department of Atomic Energy are amongst the designated members of BRIT. Enclosed as **Exhibit D** is the tax invoice issued by BRIT for selling of FDG to their client categorising FDG under classification as 3006 3000.

Capitalised terms used but not defined herein shall have the respective meanings assigned to them in the HSN, the CETSH and our various submissions/ returns filed with the department."

Additional requirement for hearing scheduled on 30.01.2018

1.	Registration No. of Central Excise or Service Tax	Central Excise - AADCN5392GEM001 Service Tax - AADCN5392GSD001
2.	Period of Registration	Central Excise w.e.f. 02/08/2016 till transition to GST Service Tax w.e.f. 06/09/2012 till transition to GST
3.	Registered Address for Central Excise or Service Tax	Thyrocare Technologies Limited Plot No D/37-1, TTC Industrial Area, MIDC Turbhe, Navi Mumbai – 400703. Maharashtra
4.	Jurisdictional Central Excise or Service Tax Offices	Central Excise – BELAPUR–I, RANGE–03 of BELAPUR–I DVN. Service Tax – Division II New – Range IV of New Belapur
5.	a) Classification of Goods & Their Central Excise Tariff Heading. b) Rate of Central Excise duty as applicable. c) Details of benefit of notification of Central Excise if any availed.	In pursuance to the enquiry conducted in respect of M/s Thyrocare Technologies Limited [Unregistered Dealer], the holding company of the Applicant, during the course of the proceeding, the applicant has been informed that the product FDG is a keen to HSN 2844 4000. Based on the same the product FDG was classified under the relevant classification and tariff heading - Radioactive chemical elements & Radioactive isotopes Rate of tax - 12.50% Benefits availed – The applicant has not availed any benefit, other than the exemption to SSI unit till the turnover has not exceeded the prescribed exemption limit.
6.	(a) Classification of Service/Services as applicable. (b) Rate / Rates of Service Tax as applicable to services provided. (c) Details of benefits of Notification of Service Tax if any availed.	The applicant is engaged in the business of providing healthcare services for diagnosis of cancer. The applicant has registered as service recipient under the relevant provisions of the Service Tax and complying with the payment of tax at the prescribed rates for the prescribed services received under reverse charge. The applicant has only availed the benefit of notification for claiming exemption of service tax since the applicant is engaged in the business of providing healthcare services.
7.	Copies of Advance Ruling Application/orders if any obtained under the provisions of Central Excise, Service Tax and Sales Tax and their present status.	None
8.	Copy of Show Cause Notices / Adjudication orders in respect of Central Excise or Service Tax if any issued during Last Five years.	The applicant has not been served with any show cause notices/ adjudication orders. Thyrocare Technologies Limited [Unregistered Dealer], the holding company engaged in the business of production of FDG in earlier financial years have been issued summons u/s 14 of the central excise act and the holding company has complied with the relevant regulations by payment of the applicable duties, with interest and penalty for the period. The applicant has also simultaneously during the course of the proceeding, voluntarily ensured to comply with the provisions of the central excise by payment of the central excise duty, interest and penalty.
9.	Cases of violation of Central Excise / Service Tax if any booked during Last Five years.	There are no any such violations of central excise/ service tax provision by the applicant apart from the mentioned above, and the Applicant has already complied with relevant provisions of the central excise by payment of duty, interest and penalty as per the direction of the Superintendent (Prev.), Central Excise, Belapur.

Additional submission dt.09.02.2018

"Any PET-CT imaging, primarily needs a "radiopharmaceutical". The radiopharmaceutical typically comprises of two components, one a "radioisotope" and another a "pharmaceutical" or a drug or a ligand. In a medical cyclotron facility, the first operation always involves the production of a radioisotope, like in our case, F-18. This radioisotope as such does not have any clinical application unless it is formulated and incorporated into a pharmaceutical for the synthesis of a radiopharmaceutical, which is Fluorodeoxyglucose or Fludeoxyglucose and popularly referred to as FDG. The synthesized radiopharmaceutical is then used for clinical imaging. The role of the "pharmaceutical" is to localize in the tissue or organ of interest to be imaged and in the process of localization carries along the radioisotope which is tagged to it. The radioisotope often also referred to as tracer, emits radiation which then are detected by the radiation detectors present in the imaging system and with the help of computer algorithms, the signals received by detectors are converted into an image.

The true clinical application therefore is derived from the synthesized radiopharmaceutical 18F-FDG at the radiochemistry laboratory and not from F-18 produced at the cyclotron.

Products of Chemicals and allied industries are classified vide Section VI under Chapter 28 to 38 CETA. Chapter 30 has been specifically carved out for chemical pharmaceuticals, by makers of the law. Thus the products or the compounds, mixtures or substance thereof used for medical treatment are specifically covered under Chapter 30 of the Section VI.

Now with reference to the classification of the product Fludeoxyglucose (18F) (the "FDG") we wish to further state as under –

Rules for interpretation of Schedules to Tariff are given in the Tariff itself. These are terms as 'General Interpretative Rule (GIR). The chapter notes are given at the beginning of each Chapter, which govern entries in that Chapter. The Chapter note prevails over heading of the chapter. For the purpose of classification of FDG if we refer the heading and sub-heading with corresponding section notes and chapter notes then apparently there is no ambiguity or confusion for classification as thus –

SrN	Extracts of the Chapter Note/ Chapter Heading, etc.	Our comments
1	*SECTION VI - PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES* *NOTES* *1. (A) Goods (other than radioactive ores) answering to a description in heading 2844 or 2845 are to be classified in those headings and in no other heading of this Schedule.* *(B) Subject to paragraph (A) above, goods answering to a description in heading 2843, 2846 or 2852 are to be classified in those headings and in no other heading of this Section.* *2. Subject to Note 1 above, goods classifiable in heading 3004, 3005, 3006, 3212, 3303, 3304, 3305, 3306, 3307, 3506, 3707 or 3808 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of this Schedule.*	The highlighted portion of Section Note 2 implies that those chemical products, which qualify to be classified under Chapter 30 (Heading 3004 etc.) are not required to be classified as chemical under Chapter 28 or 29. Further to support the fact that FDG are put up in measured doses and are supplied in packings for therapeutic or prophylactic use, the applicant has already submitted the invoices and also explained during the course of the hearing the transportation and handling of FDG.
2	*CHAPTER 28 - Inorganic chemicals, organic or inorganic compounds of precious metals, of rare-earth metals, of radioactive elements or of isotopes* *NOTES* *6. Heading 2844 applies only to:* *(a) technetium (atomic No. 43), promethium (atomic No. 61), Polonium (atomic No. 84) and all elements with an atomic number greater than 84;* *(b) natural or artificial radioactive isotopes (including those of the precious metals or of the base metals of Sections XIV and XV), whether or not mixed together;* *(c) compounds, inorganic or organic, of these elements or isotopes, whether or not chemically defined, whether or not mixed together;* *(d) alloys, dispersions (including cermets), ceramic products and mixtures containing these elements or isotopes or inorganic or organic compounds thereof and having a specific radioactivity exceeding 74 Bq/g (0.002 micro µci/g);* *(e) spent (irradiated) fuel elements (cartridges) of nuclear reactors;* *(f) radioactive residues whether or not usable.* *The term "isotopes", for the purposes of this Note and of the wording of headings 2844 and 2845, refers to:* *(i) individual nuclides, excluding, however, those existing in nature in the monoisotopic state;* *(ii) mixtures of isotopes of one and the same element, enriched in one or several of the said isotopes, that is, elements of which the natural isotopic composition has been artificially modified.*	As explained in the first part of our letter, the true clinical application is derived from the synthesized radiopharmaceutical 18F-FDG at the radiochemistry laboratory and not from F-18 produced at the cyclotron. While F-18 is the element produced in the medical cyclotron, it does not however have any clinical usage. Since the primary object of and classification under CETA is to raise revenue based on the relevant classification, resort should not be had, for purpose of classification, to the scientific and technical meaning of the terms and expressions used therein, but to their popular meaning, that is to say the meaning attached to that by those using the product. The applicant has sought guidance of the AAR to seek clarification of the radiopharmaceutical FDG and not that of the artificial radioactive isotope F-18. Anyhow the atomic number of fluorine is 9 and mass number is 18. Now reading both the section notes and chapter notes together, the intention of the legislature is to carve out those chemicals that are used as medicament or pharmaceutical product and include those under Chapter 30.
3	*CHAPTER 30 - Pharmaceutical products* *NOTES* *3. For the purposes of headings 3003 and 3004 and of Note 4(d) to this Chapter, the following are to be treated:* *(a) as unmixed products:* *(1) unmixed products dissolved in water;* *(2) all goods of Chapter 28 or 29; and* *(3) simple vegetable extracts of heading 1302, merely standardised or dissolved in any solvent;* *(b) as products which have been mixed:* *(1) colloidal solutions and suspensions (other than colloidal sulphur);* *(2) vegetable extracts obtained by the treatment of mixture of vegetable materials; and* *(3) salts and concentrates obtained by evaporating natural mineral waters.*	The chapter note to Chapter 30 further implies that for the purpose of deciding the classification of a pharmaceutical product under the headings mentioned and for the purpose of Note 4(d) [*discussed separately further*], any unmixed product dissolved in water, all goods of chapter 28 and 29 [*in this case the artificial radioactive isotope F-18, the compound of radiopharmaceutical 18F-FDG*] is to be considered as unmixed product only.
4	*CHAPTER 30 - Pharmaceutical products* *NOTES* *4. Heading 3006 applies only to the following, which are to be classified in that heading and in no other heading of this Schedule* *(a) sterile surgical catgut, similar sterile suture materials (including sterile absorbable surgical or dental yarns) and sterile tissue adhesives for surgical wound closure;* *(b) sterile laminaria and sterile laminaria tents;* *(c) sterile absorbable surgical or dental haemostatics; sterile surgical or dental adhesion barriers, whether or not absorbable;* *(d) opacifying preparations for X-ray examinations and diagnostic reagents designed to be administered to the patient, being unmixed products put up in measured doses or products consisting of two or more ingredients which have been mixed together for such uses;* *(e) blood-grouping reagents;* *(f) dental cements and other dental fillings; bone reconstruction cements;* *(g) first-aid boxes and kits;* *(h) chemical contraceptive preparations based on hormones, on other products of heading 2937 or on spermicides;* *(i) gel preparations designed to be used in human or veterinary medicine as a lubricant for parts of the body for surgical operations or physical examinations or as a coupling agent between the body and medical instruments; and*	The medicament or pharmaceutical products used as diagnostic reagents merit classification thus under this Chapter in Sub Heading 3006 3000 because – (a) they are diagnostic reagents designed to be administered to the patient, being unmixed products [*as discussed in sr. no. 3 above*] put up in measured doses products [*as discussed in sr. no. 1 above*] or products consisting of two or more ingredients which have been mixed together for such uses [*as discussed in the first paragraph of the statement of this letter*], as per para 4(d) of notes to Chapter 30. (b) they also meet the criteria of HSN, which states that "the diagnostic reagents (including microbial diagnostic reagents) covered by the heading are those administered by Ingestion, Injection, etc. Diagnostic reagents not designed to be administered to the patient (e.g. those for carrying out tests on blood. Urine etc., samples taken from a patient or for use as laboratory reagents) are excluded; they fall in the headings appropriate to the materials of which they are made (e.g. Chapter 28, Chapter 29 or heading 30.02 or 38.22). (c) the FDG (radiopharmaceutical consisting of F-18 radioactive component - based injectable products) are meant for organ/tissue imaging. The product is also administered in measured doses to the patients and are used for diagnosis in oncology, neurology and cardiology.

	(j) waste pharmaceuticals, that is, pharmaceutical products which are unfit for their original intended purpose due to, for example, expiry of shelf-life. *(k) appliances identifiable for ostomy use, that is, colostomy, ileostomy and urostomy couches cut to shape and their adhesive wafers or faceplates*	For deciding whether a product is 'medicament', following principles are relevant – (1) presence of pharmaceutical ingredients that have therapeutic or prophylactic or curative properties is relevant and proportion of medicaments is not decisive (2) even if a product is sold without a prescription of medical practitioner, it may be medicament (3) people who actually use such product must understand it to be medicament and (4) its primary function must be 'cure' and not 'care' i.e. it must be used mainly in curing or treating an ailment or disease. – *CCE v. Ciens Laboratories (2013) 42 GST 21 = 38 taxmann.com 337 = 295 ELT 3 (SC).*

During the course of the hearing reference was also made of radioactive isotope **cobalt 60** used as medicine for diagnosing and treating certain diseases. For the purpose of clarification we wish to state than in medicine, cobalt-60 is **extensively** employed as a radiation source in external radiotherapy to treat cancer, to arrest the development of cancer. Other radioactive isotopes are used as tracers for diagnostic purposes as well as in research on metabolic processes. This also coincides with our comments above in (b) in sr. no. 4.

During the course of the hearing reference was also made of classification of INN substances agreed by the harmonized system committee in April 1993 and the copy of the letter with annexure bearing reference no TAR/W/87 dated 21 June 1993 having limited/ restricted distribution is shared with us. For purpose of uniform interpretation of HS, the WCO has published detailed Explanatory Notes to various headings/ sub-headings. WCO in its various committees discussed classification of individual products and gives classification opinion on them. Such information is not binding in nature and only provides a useful guideline for classifying goods. The opinion vide circular bearing reference no TAR/W/87 dated 21 June 1993 is issued of about more than 25 years ago and since then the regulation, trade and tariff has undergone significant changes also the relevant letter is not accompanying Harmonized System Committee documents and reports and due to which evidently it would be difficult to understand as to classification questions currently under consideration. As explained in Annexure 1 to our application, the FDG manufactured by the applicant is administered to the scheduled cancer patients at the respective PETCT scanning facilities and for no other purpose. The first PETCT prototype for clinical evaluation was funded by the NCI and installed at the University of Pittsburgh Medical Center in 1998. The first commercial system itself reached the market by 2001, and by 2004, over 400 systems had been installed worldwide. Now understanding this definitely, the context in which the letter was issued in 1993 apparently differs from the context in which the present application is filed and the clarification is sought from the AAR.

Nevertheless as mentioned in our statement above, the products of chemicals and allied industries are classified vide Section VI under Chapter 28 to 38 CETA. Chapter 30 has been specifically carved out for chemical pharmaceuticals, by makers of the law. As sighted in our application and mentioned in the table below, due to the different classification being followed by registered dealers under GST, there is abnormality due to higher rates being charged by the applicant and the same is not in the interest of the ultimate beneficiary, given the general principle that where there are two competitive headings in Tariff, heading beneficial to assessee should be adopted

Tariff item	Description of goods	Unit	IGST Rate after transition to GST
(1)	(2)	(3)	(4)
2844 10 00	Radioactive elements and isotopes and compounds other than those of sub-heading 2844 10, 2844 20 or 2844 30; alloys, dispersions (including cermets), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues	kg.	18%
3006 30 00	opacifying preparations for X-ray examinations and diagnostic reagents designed to be administered to the patient, being unmixed products put up in measured doses or products consisting of two or more ingredients which have been mixed together for such uses	kg.	12%

Lastly, during the course of the hearing reference was also made as to classification and payment being followed by the applicant till this date and no protest being filed during the course of the investigation too. We wish to state thereof that –

There is no *'res judicata'* (cause or suit already decided – case already decided by the court) or *'estoppel'* (stopped from denying) in taxation matters. Either assessee or department can change its stand/ views. Assessee can change its stand (about classification, valuation, etc.). There is no law that a mistake once committed can never be rectified. Mere wrong classification of goods by assessee at one stage does not operate as estoppel/ res judicata against them for claiming classification under correct heading of *CETA – CCE v. Mahakoshal Potteries (2005) 183 ELT 289 (CESTAT).*

The Principle of *res judicata* or *estoppel* is not applicable in taxation matters CIT v. Brij Lal Lohia – 1972 84 ITR 273 (SC), MRF Ltd v. CCE – 1986 (24) ELT 273 (SC), Elson Machines v. CCE 1988 (38) ELT 571 (SC), Madras Fertilizers v. CCE (1994) 69 ELT 625 = 51 ECR 337 (SC).

The applicant and the parent company of the applicant has paid duty during investigation before issue of show cause notice due to coercion and to avoid any litigations. The amount deposited during investigation is deemed to have been paid under protest and therefore that shall not be considered a ground either to decide or dismiss this application.

In the circumstance, to clear the ambiguity, we sincerely request the AAR to pass an appropriate order based on our application, the submissions subsequent, the clarification during the course of the hearing and on the basis of further final submissions vide this letter.

Capitalised terms used but not defined herein shall have the respective meanings assigned to them in the respective regulation, notifications and our various submissions filed with the department."

03. CONTENTION – AS PER THE CONCERNED OFFICER

The submission, as reproduced verbatim, could be seen thus-

"Question (1)

(i):- The product fludeoxyglucose or 'FDG' cannot be classified under Chapter 30063000 as the same is rightly classified under Chapter Sub Heading 28444000. The relevant Section Note of Section VI of Central Excise Tariff Act, 1985 is extracted below

1. (A) Goods (Other than radioactive ores) answering to a description in heading 2844 or 2845 are to be classified in those headings and in no other heading of this Schedule.

(B) .....

2. Subject to Note 1 above, goods classifiable in heading 3004,3005,3006,3212,3303,3304,3305,3306,3307,3506,3707 or 3808 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of this Schedule.

(ii) The description of goods under Chapter Sub Heading 28444000 is as under:-

"Radioactive elements and isotopes and compounds other than those of Sub Heading 2844 10, 2844 20 or 2844 30; alloys, dispersions (including cermets), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues"

(iii) The product fludeoxyglucose –F18 manufactured by Applicant is a Radioisotope obtained artificially through Cyclotron machine and answers to the description under Chapter Sub Heading 28444000.

(iv) It is clear from the contents and detailed explanation of Note 2 given in Section VI above that the goods mentioned in Note 1 (A) i.e goods falling under Chapter 2844 or 2845 will not be classified under any other heading irrespective of the products being put up in measured doses or for retail sale. Hence, the product falling under chapter 2844 or 2845 are to be classified in those headings only and no other heading of the Schedule. Accordingly, the products falling under Chapter Sub Heading 28444000 will merit classification in Chapter 28 only.

Question (2) -

It is clear from the contents and detailed explanation of Note 2 given in Section VI above that the goods mentioned in Note 1 (A) i.e goods falling under Chapter 2844 or 2845 will not be classified under any other heading irrespective of the products being put up in measured doses or for retail sale. Hence, the product falling under chapter 2844 or 2845 are to be classified in those headings only and no other heading of the Schedule. Accordingly, the products falling under Chapter Sub Heading 28444000 will merit classification in Chapter 28 only.

Annexure 1 statement of facts

Point (1 to 3):- No Comments

Point (4):- The Applicant was apprised about excisability of the product i.e FDG on 26.07.2016 at time of recording of statement of Shri Sachin Ashok Salvi, General Manager, Finance of the applicant under Section 14 of Central Excise Act, 1944. In reply to the question as to whether the product i.e 18F-FDG(Fludeoxyglucose) attracts Central Excise Duty and is classifiable under Chapter Sub Heading 28444000 of CETA 1985, Shri Sachin Ashok Salvi replied that the product FDG is Excisable and attracts Central Excise Duty. Further, the applicant in their application dated 02/08/2016 for Central Excise Registration (Form A-1) has also classified their excisable goods manufactured i.e Radioactive chemical elements and radioactive isotopes(Including the fissile or fertile chemical elements and isotopes) under Chapter Sub Heading 28444000. This proves that even the applicant accepted the contention of the department and started classifying their product i.e 18F-FDG(Fludeoxyglucose) under Chapter 28 to discharge Central Excise Duty at appropriate rate.

Point (5):- No Comments

Annexure-2 – Applicant's view points and submission on issues on which the advance ruling is sought

Point (1 to 2):- No Comments

Point (3)(i) :- Applicant has contended that the Department view of classification of subject goods under chapter sub heading 2844 suffers from legal infirmity, mis-appreciation of facts and wrong invocation of statutory provisions. However, the contention of the applicant is factually incorrect and devoid of any merit and deserves to be dismissed. The applicant relied on Note 2 of Section VI of CETA 1985 in support of his contention. However, Note 2 of Section VI of CETA 1985 has to be read in Juxtaposition and subject to Note 1 of Section VI. It is clear from the contents and detailed explanation of Note 2 given in Section VI above that the goods mentioned in Note 1 (A) i.e goods falling under Chapter 2844 or 2845 will not be classified under any other heading irrespective of the products being put up in measured doses or for retail sale. Hence, the product falling under chapter 2844 or 2845 are to be classified in those headings only and no other heading of the Schedule. Accordingly, the products falling under Chapter Sub Heading 28444000 will merit classification in Chapter 28 only.

(ii) It is further substantiated by the description of goods given under Chapter Sub Heading to 28444000 as follows:-

"Radioactive elements and isotopes and compounds other than those of Sub Heading 2844 10, 2844 20 or 2844 30; alloys, dispersions (including cermets), ceramic products and mixture containing these elements, isotopes or compounds; radioactive residues"

(iii) Further Shri Sachin Ashok Salvi, General Manager, Finance also admitted in his statement dated 26.07.2016 that the product fludeoxyglucose –F18 manufactured by Applicant is a Radioisotope obtained artificially through Cyclotron machine. He further admitted that their product i.e FDG is excisable and attract Central Excise Duty. From the reading of Chapter Sub Heading 28444000 read with Section Note 2 of Section VI that the product manufactured by the applicant will be rightly classifiable under Chapter 28444000 and not under any other Chapter heading in terms of Note 1(A) of Section VI of CETA 1985

It is clear from the contents and detailed explanation of Note 2 given in Section VI that the goods mentioned in Note 1 (A) i.e goods falling under Chapter 2844 or 2845 will not be classified under any other heading irrespective of the products being put up in measured doses or for retail sale. Hence, the product falling under chapter 2844 or 2845 are to be classified in those headings only and no other heading of the Schedule. Accordingly, the products falling under Chapter Sub Heading 28444000 will merit classification in Chapter 28 only.

(iv) It is further clarified in HSN under Chapter 2844 that Radioactive isotopes of these same elements obtained artificially (e.g. Be 10,**F 18**, Al 29, P 32, Mn 54) are however to be considered as isotopes. This clarifies that isotope of element F18 are to be considered as isotope only and the same would be appropriately covered under the definition of Chapter 28444000. Hence, the contention of applicant regarding classification of their product under Chapter 30 is based on mis-interpretation of Section Note.

(v) As per CETA, 1985 read with the relevant portions of Harmonized Commodity Description and Coding System, Vol-I, it is evident that FDG-18 would fall under Chapter Heading 2844 of CETA, 1985 as the product falling under chapter 2844 or 2845 are to be classified in those heading only and no other heading of this schedule. Accordingly, the products falling under Chapter Sub Heading 28444000 merit classification in Chapter 28 only.

(c) The Explanatory notes from Harmonized Commodity Description and Coding System, Vol-I, relating to chapter heading 28.44 in para III (c) (2) mentions as under:

"(2) Compounds of radioactive isotopes referred to under (III) (B) above.
Artificial radioactive isotopes and their compounds are used:
(a) .....
(b) In medicine, e.g for **diagnosing** or treating certain diseases (cobalt 60, iodine 131, gold 198, phosphorous 32 etc."
(c) .....
(d) .....

In view of the specific mention of its use in medicine for diagnostic or treatment purpose in the Explanatory note of chapter subheading 2844 of Harmonized Commodity Description and Coding System, the applicant's claim regarding their product being a Diagonstic reagents and hence liable to be classified under chapter – heading 3006 is devoid of merits.

Point (4) (i):- The contention of the Applicant that the product falls under Chapter Sub Heading 30063000 is not correct. It is clear from the contents and detailed explanation of Note 2 given in Section VI above that the goods mentioned in Note 1 (A) i.e goods falling under Chapter 2844 or 2845 will not be classified under any other heading irrespective of the products being put up in measured doses or for retail sale. Hence, the product falling under chapter 2844 or 2845 are to be classified in those headings only and no other heading of the Schedule. Accordingly, the products falling under Chapter Sub Heading 28444000 will merit classification in Chapter 28 only. As per the Explanatory note to Chapter Sub Heading 2844 of Harmonised Commodity Description and Coding System, Vol-I, Page No. VI-2844-1, VI-2844-2, VI-2844-3 and VI-2844-4 wherein it is clearly stated that Chapter Heading 2844 and 2845 covers not only isotopes in their pure state but also chemical elements whose natural isotopic composition has been artificially modified by enriching the elements in some of their isotopes or by converting through a nuclear reaction, some isotopes into other, artificial isotopes, Radioisotopes of these same elements obtained artificially (e.g.Be 10, **F 18**, Al 29, P 32, Mn 54) are however to be considered as isotopes.

(ii) In support of Revenue's contention that Fludeoxyglucose **F 18** (FDG) is classifiable under Chapter Sub-Heading 28444000, please find enclosed herewith classification decision of International Non Proprietary Name (INN) Substances agreed by the Harmonized System Committee of General Agreement on Tariff & Trade (Now World Trade Organization ie WTO) for consideration.

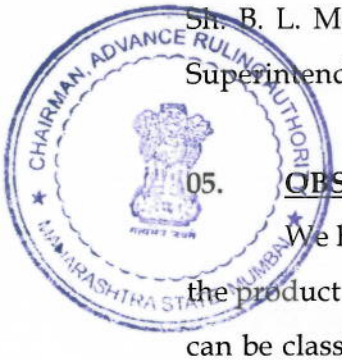
(iii) In view of the above, the products Fludeoxyglucose **F 18** (FDG) is classifiable under Chapter Sub Heading 28444000 of CETA, 1985.

(5):- This office has issued Show Cause Notice to M/s Board of Radiation and Isotope Technology (BRIT) for inter-alia classifying goods including F18 under Chapter Sub Heading 2844 and the adjudication of the same is under process. As instructed the copy of Show Cause Notice enclosed herewith.

3. In view of the above submissions the application of M/s Nueclear Healthcare Ltd, Navi Mumbai should be decided by rejecting the contention of the applicant as the subject goods merit classification in Chapter 28."

04. HEARING

The case was taken up for hearing on dt.30.01.2018, dt.07.02.2018 and dt.15.02.2018 when Sh. Sachin Salvi (Chartered Accountant) attended and reiterated the contention as made in the written submission that the product be classified under Tariff Heading 3006. Sh. M. V. Gholap, Assistant Commissioner (AC), Belapur GST Division-II attended the hearing on dt.30.01.2018. Sh. B. L. Meena, AC, Belapur GST Division-III, the concerned officer and Sh. R. V. Salaskar, Superintendent were present during the hearings on dt.07.02.2018 and dt.15.02.2018.



05. OBSERVATIONS

We have gone through the facts of the case. The issue put before us is the classification of the product 'Fludeoxyglucose' or 'FDG'. It has been queried as to whether the impugned product can be classified under Chapter 3006 3000 of the Central Excise Tariff Act, 1985. We have seen the invoices issued by the applicant wherein the product "^{18}F-FDG (Fluorodeoxyglucose)"is mentioned as falling under the HSN Code of 28444000 and attracting GST @18%. The applicant has also submitted the invoice issued by the Board of Radiation and Isotope Technology wherein the product "FDG 18" is shown as falling under HSN Code 30063000" and attracting GST @12%. The reason to mention the aforesaid is the applicant's humble plea during hearing to clear the controversy surrounding the classification so as to have a uniform tax discharge by all dealing with the said commodity. However, it is seen that the applicant has given an elaborate submission in favour of the product falling under Central Excise Tariff Heading 30063000. Further, it is seen that the applicant has contended that classification under Chapter Subheading 2844 of the Central Excise Tariff Act, 1985, suffers with legal infirmity, mis-appreciation of facts and wrong invocation of statutory provisions. To appreciate the issue, it would be better if we reproduce the competing Custom Tariff Headings and Tariff items thus–

2844		RADIOACTIVE CHEMICAL ELEMENTS AND RADIOACTIVE ISOTOPES (INCLUDING THE FISSILE OR FERTILE CHEMICAL ELEMENTS AND ISOTOPES) AND THEIR COMPOUNDS; MIXTURES AND RESIDUES CONTAINING THESE PRODUCTS
2844 10 00	-	Natural uranium and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing natural uranium or natural uranium compounds
2844 20 00	-	Uranium enriched in U_{235} and its compounds; plutonium and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing uranium enriched in U_{235}, plutonium or compounds of these products
2844 30	-	*Uranium depleted in U_{235} and its compounds; thorium and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing uranium depleted in U_{235}, thorium or compounds of these products :*
2844 30 10	---	Uranium depleted in U_{235} and thorium and their alloys, unwrought or wrought and compounds thereof
	---	*Compounds of thorium or of uranium depleted in U_{235} :*
2844 30 21	----	Thorium oxide
2844 30 22	----	Thorium hydroxide
2844 30 23	----	Thorium nitrate
2844 30 29	----	Other
2844 30 30	---	Waste and scrap of uranium depleted in U_{235} or of thorium
2844 30 90	---	Other
2844 40 00	-	Radioactive elements and isotopes and compounds other than those of sub-headings 2844 10, 2844 20 or 2844 30; alloys, dispersions (including cermets), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues
2844 50 00	-	Spent (irradiated) fuel elements (cartridges) of nuclear reactors

3006		PHARMACEUTICAL GOODS SPECIFIED IN NOTE 4 TO THIS CHAPTER
3006 10	-	Sterile surgical catgut, similar sterile suture materials (including sterile absorbable surgical or dental yarns) and sterile tissue adhesives for surgical wound closure; sterile laminaria and sterile laminaria tents; sterile absorbable surgical or dental haemostatics; sterile surgical or dental adhesion barriers, whether or not absorbable :
3006 10 10	---	Sterile, surgical catgut and similar sterile suture materials (including sterile absorbable surgical or dental yarns) and sterile tissue adhesives for wound closure
3006 10 20	---	Sterile laminaria and sterile laminaria tents, sterile absorbable surgical or dental haemostatics, sterile surgical or dental adhesion barriers, whether or not absorbable
3006 20 00	-	Blood grouping reagents
3006 30 00	-	Opacifying preprations for X-ray examinations; diagnostic reagents designed to be administered to the patient
3006 40 00	-	Dental cements and other dental fillings; bone reconstruction cements
3006 50 00	-	First-aid boxes and kits
3006 60	-	*Chemical contraceptive preparations based on hormones, or other products of heading 2937 or on spermicides :*
3006 60 10	---	Based on hormones
3006 60 20	---	Based on other products of heading 2937
3006 60 30	---	Based on spermicides
3006 70 00	-	Gel preparations designed to be used in human or veterinary medicine as a lubricant for parts of the body for surgical operations or physical examinations or as a coupling agent between the body and medical instruments
	-	*Other:*
3006 91 00	--	Appliances identifiable for ostomy use
3006 92 00	--	Waste pharmaceuticals

To understand which of the Headings would cover the impugned product, we need to understand the product and the principles of interpretation. The applicant has preferred to refer to Wikipedia to explain us the impugned product. We see thus –

- **https://en.wikipedia.org/wiki/Fludeoxyglucose_(18F)**
  Fludeoxyglucose (^{18}F) (INN), or **fludeoxyglucose F 18** (USAN and USP), also commonly called **fluorodeoxyglucose** and abbreviated **[^{18}F]FDG**, **^{18}F-FDG** or **FDG**, is a **radiopharmaceutical used in the medical imaging modality positron emission tomography (PET)**.

- **http://www.who.int/medicines/publications/pharmacopoeia/Radgenmono.pdf**
  Introduction
  Radiopharmaceuticals are unique medicinal formulations containing radioisotopes which are used in major clinical areas for diagnosis and/or therapy.
  Definition
  Radiopharmaceuticals can be divided into four categories:
  Radiopharmaceutical preparation A radiopharmaceutical preparation is a **medicinal product in a ready-to-use form suitable for human use that contains a radionuclide**. The radionuclide is integral to the medicinal application of the preparation, making it appropriate for one or more diagnostic or therapeutic applications.

Radionuclide generator A system in which a daughter radionuclide (short half-life) is separated by elution or by other means from a parent radionuclide (long half-life) and later used for production of a radiopharmaceutical preparation.
Radiopharmaceutical precursor A radionuclide produced for the radiolabelling process with a resultant radiopharmaceutical preparation.
Kit for radiopharmaceutical preparation In general a vial containing the non radionuclide components of a radiopharmaceutical preparation , usually in the form of a sterilized, validated product to which the appropriate radionuclide is added or in which the appropriate radionuclide is diluted before medical use. **In most cases the kit is a multidose vial and production of the radiopharmaceutical preparation may require additional steps such as boiling, heating, filtration and buffering.** Radiopharmaceutical preparations derived from kits are normally intended for use within 12 hours of preparation.

- **www.aerb.gov.in/index.php/english/regulatory-facilities/radiation-facilities/application-in-medicine/medical-cyclotron**
Medical Cyclotron - A cyclotron is a machine used to make relatively **short lived radioisotopes** (radioactive atoms) that can be used for medical imaging and research.

- **http://news.chinatungsten.com/en/tungsten-information/97193-ti-12449**
Tungsten is used as shielding material in radiation medicine. It always uses tungsten container when transporting fluorodeoxyglucose, whose high energy makes the fluoro-18 lead container unusable.
Fluorodeoxyglucose is a fluoro derivative of 2-deoxyglucose, usually referred to as 18F-FDG or FDG. FDG is most commonly used in positron emission tomography (PET) medical imaging equipment. **After injecting FDG into the patient, the PET scanner can construct an image that reflects the distribution of the FDG in vivo. Then, the nuclear medicine physician or radiologist evaluates these images to make a diagnosis of various medical health conditions.**
18F-FDG can be used to assess glucose metabolism in the heart, lungs, and brain. FDG-PET can be used for cancer diagnosis, staging and treatment monitoring, especially for Hodge's disease, non Hodge's lymphoma, colorectal cancer, breast cancer, melanoma, and lung cancer.
In addition, FDG-PET also has been used for the diagnosis of Alzheimer's disease. In the field of nuclear medicine, **compound 18F-FDG**, besides its important use in cardiology and neurology, it also exhibits cancer tissues that can be detected by conventional methods, or correct the misdiagnosis of these diseases.

- **Essentials of Inorganic Chemistry: For Students of Pharmacy, Pharmaceutical Sciences and Medicinal Chemistry by KATJA A. STROHFELDT - Chapter 10 Radioactive Compounds and Their Clinical Application**

10.2 Radiopharmacy: dispensing and protection
Radiopharmacy deals with the manufacture and dispensing of radioactive materials that are used as radioactive medicines (or better known as *radiopharmaceuticals*). Radiopharmaceuticals can be used as diagnostic or therapeutic tools. Radionuclides that are used for a diagnosis should have as little an impact as possible on the health of the patient.

10.4 Radiopharmaceuticals for imaging
Radiopharmaceuticals are typically administered intravenously and then distributed to a particular organ. The molecule itself, and not the radiolabelling, will determine to which organ the radioactive molecule is transported. γ-Radiation is detected externally by using a special scintillation detector, also known as a *gamma camera*. The camera captures the emitted radiation and forms a two-dimensional image. This diagnostic test is also called *scintigraphy*.

In contrast, PET produces a three-dimensional image of the functional processes in the human body. The method is based on the use of positron-emitting radionuclides and their indirectly emitted gamma rays. Radionuclides, the so-called tracers, are introduced to the body as parts of biologically active molecules. PET also uses gamma cameras to detect the internally applied radiation, but in modern scanners, three-dimensional images are often achieved with the aid of a CT X-ray scan performed at the same time as part of the same machine.

Diagnostic X-ray uses external radiation, which is sent through the body to produce a two-dimensional image, whereas scintography is based on the internal accumulation of radionuclides.

10.4.1 99mTechnetium

10.4.2 18Fluoride: PET scan
Fluorine has the chemical symbol F and atomic number 9 and is the most electronegative element. It belongs to group 17 of the periodic table, the so-called halogens. Fluorine typically exists as a diatomic molecule at room temperature.

There are 18 isotopes known of fluorine, but only 1 (19F) is stable. Most of the radioactive isotopes have a very short half-life, mostly <1min. **Only the radioisotope 18F has a longer half-life** of around 110 min and is clinically used (Figure 10.23).

18F is a positron-emitting radioisotope and is used in radiopharmaceutical imaging such as PET scanning. **Two compounds, namely fluorodeoxyglucose (18F-FDG)** and derivatives of 18F choline, are under intense clinical investigation and/or use.

18F-FDG is a glucose derivative that contains a radiolabel (18F) at the 2′ position replacing the hydroxyl group. 18F-FDG is administered intravenously and is used as an assessment of problems with glucose metabolism, especially in the brain, often associated with epilepsy and in cancer. Areas where an increased absorption of 18F-FDG are visible correlate to areas where an increased glucose metabolism is present.b18F-FDG is distributed around the body similar to glucose and is cleared renally. There are no known contraindications known to 18F-FDG (Figure 10.24).

18F-FDG is the main radioimaging agent used in PET scanning. Examples include studies of heart, where it is used to differentiate between dead and live tissue in order to assess the myocardium. In neurology, it can be used to diagnose dementia, seizure disorders or tumours of the brain. 18F-FDG is generally used to assess the extent of the tumour in a cancer patient. Cancerous tissue is characterised by increased cell proliferation, which requires energy, and therefore an increased amount of glucose. This leads to an accumulation of 18F-FDG in malignant tumours and allows judging the degree of metastasis formed. This information is important for any surgical procedure and also for the initial assessment of the cancer stage.

Unfortunately, there are limitations to the use of 18F-FDG, as its uptake is not very specific. As a result, other conditions can also cause an accumulation of 18F-FDG and can lead to misdiagnosis. These conditions include inflammation and healing of wounds, which also show increased glucose metabolism.

Therefore, a variety of other 18F-labelled compounds are under intense scrutiny as alternative PET scanning agents, mainly compounds with a more specific biological pathway. This includes 18F-choline. Choline is a compound incorporated into the cell membrane and therefore cells dividing at a fast rate have an increased need for this substance. Studies for a range

of tumours were undertaken, but most studies focussed on prostate cancer. In comparison to 18F-FDG, 18F-choline showed less activity in the bladder and a prolonged elimination via the kidneys. Additionally, biological processes other than cancer also include rapid division of cells and can lead to misdiagnosis (Figure 10.25).

10.4.3 67Gallium: PET

....."

We have certain inferences from the above that –

- ***Fluorine has the chemical symbol F and atomic number 9 and is the most electronegative element.***
- ***18F is a radioisotope.***
- ***18F is a positron-emitting radioisotope and is used in radiopharmaceutical imaging such as PET scanning.***
- ***Two compounds, namely fluorodeoxyglucose (18F-FDG) and derivatives of 18F choline, are under intense clinical investigation and/or use.***

Thus, it can be seen that Chapter 10 is about "Radioactive Compounds"and 18F-FDG is a compound of the radioisotope 18F. In this background, we see the Customs Tariff Heading 2844 which is for "RADIOACTIVE CHEMICAL ELEMENTS AND RADIOACTIVE ISOTOPES (INCLUDING THE FISSILE OR FERTILE CHEMICAL ELEMENTS AND ISOTOPES) AND THEIR COMPOUNDS; MIXTURES AND RESIDUES CONTAINING THESE PRODUCTS". Thus, the Heading 2844 covers radioactive isotopes and their compounds. 18F-FDG being a compound of the radioisotope 18F, it would fall in this Heading 2844.

However, it has been argued that the impugned product being a chemical pharmaceutical, falls in the Heading 30.06. Since the whole gamut of the arguments revolve around the Harmonized Commodity Description and Coding System Explanatory Notes (HSN), we may now look at the relevant portion of the said Notes thus –

- **SECTION VI - PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES NOTES**

1. (A) Goods (other than radioactive ores) answering to a description in heading 28.44 or 28.45 are to be classified in those headings and in no other heading of the Nomenclature.

(B) Subject to paragraph (A) above, goods answering to a description in heading 28.43, 28.46 or 28.52 are to be classified in those headings and in no other heading of this Section.

2. Subject to Note 1 above, goods classifiable in heading 30.04, 30.05, **30.06**, 32.12, 33.03, 33.04,33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 **by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of the Nomenclature.**

GENERAL

Note 1.

Under the provisions of paragraph (A) of this Note, all radioactive chemical elements and radioactive isotopes, and compounds of such elements and isotopes (whether inorganic or organic, and whether or not chemically defined), are classified under heading 28.44, even though they could also fall under some other heading of the Nomenclature. Thus, for example, radioactive sodium chloride and radioactive glycerol fall in heading 28.44 and not in heading 25.01 or 29.05. Similarly, radioactive ethyl alcohol, radioactive gold, and radioactive cobalt are in all circumstances classified in heading 28.44. It should be noted, however, that radioactive ores are classified in Section V of the Nomenclature.

In the case of non-radioactive radioactive isotopes and their compounds, the Note provides that these (whether inorganic or organic, and whether or not chemically defined) are classified in heading 28.45 and not elsewhere in the nomenclature does the isotope of carbon is classified under heading 28.45 and not under heading 28.03.

Paragraph (B) of the Note provides that goods described in heading 28.43, 28.46 or 28.52 are to be classified under whichever of those headings of those headings is appropriate and under no other heading in Section VI, provided always they are not radioactive or in the form of isotopes (in which case they are classified in either heading 28.44 or heading 28.45). This paragraph of the Note provides, therefore, that, e.g., silver caseinate is classified in heading 28.43 and not in heading 35.01, and that silver nitrate, even when put up for retail sale ready for photographic use, is classified in heading 28.43 and not in heading 37. 07.

Note 2.

Section Note 2 provides that goods **(other than those described in heading 28.43 to 28.46** or 28.52) which are covered by heading 30.04, 30. 05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37. 07 or 38.08 **by reason of being put up in measured doses or for retail sale, are to be classified in those headings notwithstanding that they could also fall in some other heading of the Nomenclature.** For example, sulphur put up for retail sale for therapeutic purposes is classified in heading 30.04 and not in heading 25.03 or 28.02, and dextrin put up for retail sale as a glue is classified in heading 35.06 and not in heading 35.05.

- **CHAPTER 28 – NOTES**

6. Heading 28.44 applies only to :

(a) Technetium (atomic No. 43), promethium (atomic No. 61), polonium (atomic No.84) and all elements with an atomic number greater than 84;

(b) Natural or artificial radioactive isotopes (including those of the precious metals or of the base metals of Sections XIV and XV), whether or not mixed together;

(c) **Compounds, inorganic or organic, of these elements or isotopes, whether or not chemically defined, whether or not mixed together;**

.....

(f) Radioactive residues whether or not usable.

The term "isotopes", for the purposes of this Note and of the wording of headings 28.44 and 28.45, refers to :

- individual nuclides, excluding, however, those existing in nature in the monoisotopic state;
- mixtures of isotopes of one and the same element, enriched in one or several of the said isotopes, that is, elements of which the natural isotopic composition has been artificially modified.

The term "isotopes ", for the purposes of this Note and of the wording of headings 28.44 and 28.45, refers to :

- Individual nuclides, excluding, however, those existing in nature in the monoisotopic state;
- Mixtures of isotopes of one and the same element, enriched in one or several of the said isotopes, that is, elements of which the natural isotopic composition has been artificially modified.

GENERAL

(C) Products which remain classified in Chapter 28, even when they are not separate chemical elements nor separate chemically defined compounds

Heading 28.44 - Radioactive elements, radioactive isotopes, or compounds (inorganic or organic) and mixtures containing these substances

- **HEADING 28.44 – NOTES**

(I) Isotopes

.....

It should be noted that elements existing in nature in the monoisotopic state, e.g., beryllium 9, fluorine 19, aluminium 27, phosphorus 31, manganese 55, etc., are not to be considered as isotopes, but are to be classified, in either the free or the combined state, according to the case, in the more specific headings relating to chemical elements or to their compounds.

Radioactive isotopes of these same elements obtained artificially (e.g. Be 10, **F 18**, Al 29, P 32, Mn 54) **are, however, to be considered as isotopes.**

.....

(III) Radioactive chemical elements, radioactive isotopes and their compounds; Mixtures and residues containing these products

.....

(C) Radioactive compounds; mixtures and residues containing radioactive substances

The radioactive chemical elements and isotopes of the present heading are often used in the form of compounds or products which are "labelled" (i.e., contain molecules with one or more radioactive atoms). Such compounds remain classified in this setting, even when dissolved or dispersed in, or mixed naturally or artificially with, other radioactive or non-radioactive materials. These elements and isotopes are also classified in this heading when in the form of alloys, dispersions or cermets.

.....

Artificial radioactive isotopes and their compounds are used :

(a) In industry .....

(b) In medicine, e.g., for diagnosing or treating certain diseases (cobalt 60, iodine 131, gold 198, phosphorus 32, etc.).

(c) In agriculture, ...

(d) In biology, ...

Radioactive isotopes and their compounds are normally put up in the form of powders, solutions, needles, thread or sheets. They are generally contain in glass ampoules, in hollow platinum needles, in stainless steel tubes, etc., which are **packed in anti-radiation metal outer containers** (generally of lead), the choice of the thickness of which depends on the degree of radioactivity of the isotopes. In accordance with certain international agreements, a special label must then be affixed to the container, giving particulars of the isotope contained therein and its degree of radioactivity.

- **CHAPTER 30 – NOTES**

4. Heading 30.06 applies only to the following, which are to be classified in that heading and in no other heading of the Nomenclature :

(d) Opacifying preparations for X-ray examinations and **diagnostic reagents designed to be administered to the patient, being unmixed products put up in measured doses or** products consisting of two or more ingredients which have been mixed together for such uses;

- **HEADING 30.06 – NOTES**

(6) Opacifying preparations for X-ray examinations and **diagnostic reagents designed to be administered to the patient, being unmixed products put up in measured doses or** products consisting of two or more ingredients which have been mixed together for such uses.

The opacifying preparations are used in X-ray examination of internal organs, arteries, veins, urinary passages, bile duct, etc. They are based on barium sulphate or other substances opaque to X-rays and may be put up for injection of for oral administration (e.g., barium meal).

The diagnostic reagents (including microbial diagnostic reagents) covered by the heading are those administered by ingestion, injection, etc.

Diagnostic reagents not designed to be administered to the patient (e.g., those for carrying out tests on blood, urine, etc., samples taken from a patient or for use as laboratory reagents) are excluded; they fall in the headings appropriate to the materials of which they are made (e.g., Chapter 28, Chapter 29 or heading 30.02 or 38.22).

We may also have a look at the following :

- **http://rasayanjournal.co.in/vol-4/issue-2/42.pdf**

DIAGNOSTIC AGENTS-TYPES AND APPLICATIONS: A DISCUSSION

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Basically, diagnostic agents includes chemical compounds of inorganic or organic nature, most of these being modified in their structural moeity, so as to become specific for their test reactions. These modifications make them biochemicals, depending upon their constitution and functional groups. Inorganic chemicals are not directly functioning as diagnostic agents, but their use, by some way, is essential either to control the reaction process or to provide the necessary conditions for the systematic analysis. Beside the organic reagents used, dyes and stain are an important class of diagnostic agents especially for quantitative determination by colorimetry, which is now the best tool for diagnosis. **Radioactive tracers are extensively used in routine clinical diagnosis.** Important examples are, studies of the functioning of thyroid gland and to locate the exact site of the tumors of brain by using radioactive iodine, studies of blood circulation time using radioactive sodium and chromium, studies of obscure anaemias and other blood disorders using radioactive iron and studies of important body functions such as digestion, metabolism and excretion. The functioning of different parts and organ systems of the body such as the liver, the kidneys, etc. is also studied by using radioactive isotopes, thus enabling the diagnosis of different disease states.

Broadly, we can divide the various compounds used as diagnostic agents into four major classes as :

A. Inorganic and organic compounds used directly.
B. Dyes and stains specifically for use in end point or initial rate colorimetry.
C. Radioactive tracers.
D. Culture-media chemical-basic constituent being Agar.

.....

(C) Radioactive Tracers[9,10]

Name and Symbol	Form	Use (Diagnostic)
Americium ^{241}Am	Encapsulated source	In bone mineral analyzer.
.....	.....	.....
Cobalt ^{60}Co and ^{57}Co	Radioactive Vitamin B12	For absence of intrinsic factor (P.A.) or defect in absorption (sprue). Metabolic studies.
.....	.....	.....
Fluorine ^{18}F	**Sodium fluoride (reactor produced)**	**Bone scan**

- **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3478111/**

Fluorine-18 is one of the several isotopes of fluorine that is routinely used in radiolabeling of biomolecules for PET; because of its positron emitting property and favorable half-life of 109.8 min. The biologically active molecule most commonly used for PET is 2-deoxy-2-^{18}F-fluoro-β-D-glucose (^{18}F-FDG), an analogue of glucose, for early detection of tumors. .....
Based on information from the Isotopes of Fluorine Wikipedia page [20], fluorine has several isotopes, ^{19}F, ^{18}F, ^{17}F, ^{20}F, and ^{21}F. Except for ^{19}F, these isotopes are radioactive and have very short half-lives, especially ^{17}F, ^{20}F and ^{21}F. ^{19}F and ^{18}F are used by the scientific community, especially ^{18}F, which has a half-life of 109.8 min. ^{18}F emits a positron that collides with an electron, which is called an "annihilation reaction" and produces two photons with 511 Kev (gamma radiation) 180° apart [21-23]. Because of its short half-life and positron emission, ^{18}F is widely used in molecular imaging of biological and biochemical processes, including early detection of many diseases and assessment of treatment response by positron emission tomography (PET) [24-34].

PET is a nuclear medicine imaging technique that produces a three-dimensional image of functional processes in the body [27,28]. The system detects pairs of gamma rays emitted indirectly through an annihilation reaction by a positron-emitting radionuclide, such as ^{18}F, which has been injected into the body through a biologically active molecule as a carrier. Three-dimensional images of the radiotracer concentrations within the body are then reconstructed by a computer using appropriate software and analysis. **The biologically active molecule most commonly used for PET is 2-deoxy-2-^{18}F-fluoro-β-D glucose (^{18}F-FDG), an analogue of glucose, which is used for early detection of tumors** [29-31] and assessment of response to cancer therapy [24,26]. ..... Although ^{18}F-FDG is the most common PET tracer, other ^{18}F-labeled molecules are also used in PET imaging of tumor proliferation [32-34], herpes simplex virus-1 thymidine kinase (HSV1-tk) gene expression [35-38], and many receptor-ligand interactions [39-42].

The nucleophilic radiofluorination reaction has been used to synthesize **many compounds, including ^{18}F-FDG** (Figure 3A) [29]. Given the popularity and wide use of ^{18}F-FDG, this compound has been synthesized using both nucleophilic and electrophilic reactions

- **http://www.nueclear.com/pet-ct/ - WEBSITE OF THE APPLICANT**

The radioisotope 118F in the ^{18} F – FDG / Sodium Fluoride has a very short half-life of 110 minutes. During short-supply or no supply of this drug, it is likely that few or all scheduled appointments may have to be cancelled or altered.

We have referred to many an informative articles to understand the dispute at hand. We have seen above that 18F is a radioisotope AND fluorodeoxyglucose (18F-FDG) is a compound. And since all point to the impugned product being a compound of the radioisotope 18F, the Tariff Heading which covers the situation is Heading 2844 which is for "**RADIOACTIVE CHEMICAL ELEMENTS AND RADIOACTIVE ISOTOPES (INCLUDING THE FISSILE OR FERTILE CHEMICAL ELEMENTS AND ISOTOPES) AND THEIR COMPOUNDS; MIXTURES AND RESIDUES CONTAINING THESE PRODUCTS**". Heading 2844 covers compounds of radioactive isotopes. And it has been specifically provided that –

- All radioactive chemical elements and radioactive isotopes, and compounds of such elements and isotopes (whether inorganic or organic, and whether or not chemically defined), are classified under heading 28.44, even though they could also fall under some other heading of the Nomenclature.
- Goods (other than radioactive ores) answering to a description in heading 28.44 or 28.45 are to be classified in those headings and in no other heading of the Nomenclature.
- The Heading 2844 itself acknowledges the fact that –
    - *the radioactive chemical elements and isotopes of the heading 2844 are often used in the form of compounds or products which are "labelled" (i.e., contain molecules with one or more radioactive atoms). Such compounds remain classified in this setting, even when dissolved or dispersed in, or mixed naturally or artificially with, other radioactive or non-radioactive materials.*
    - *artificial radioactive isotopes and their compounds are used in medicine, e.g., for diagnosing or treating certain diseases (cobalt 60, iodine 131, gold 198, phosphorus 32, etc.).*

The applicant has informed that the impugned product is transported in specialised shielded tungsten containers. Articles from the Internet also reveal that radioactive isotopes and their compounds are packed in anti-radiation metal outer containers. In view of all above, we do not have an iota of doubt that the impugned product, a compound of the radioisotope 18F, is covered by the Heading 2844.

We see that the applicant's argument revolves around the point that –

A chemical pharmaceutical, falls in the Heading 30.06.

- Heading 3006 covers diagnostic reagents.
- Diagnostic reagents (including microbial diagnostic reagents) covered by the heading are those administered by Ingestion, Injection, etc.
- Diagnostic reagents not designed to be administered to the patient (e.g. those for carrying out tests on blood. Urine etc., samples taken from a patient or for use as laboratory reagents) are excluded; they fall in the headings appropriate to the materials of which they are made (e.g. Chapter 28, Chapter 29 or heading 30.02 or 38.22).

While relying on the above, the applicant seems to ignore the inherent differentiation as has been laid down in the HSN (HSN forms the basis for Customs Tariff) and which is -

- General Note 1 of Section VI [PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES] provides that all radioactive chemical elements and radioactive isotopes, and compounds of such elements and isotopes (whether inorganic or organic, and whether or not chemically defined), are classified under heading 28.44, even though they could also fall under some other heading of the Nomenclature.

- General Note 2 of Section VI [PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES] provides that goods (other than those described in heading 28.43 to 28.46 or 28.52) which are covered by heading 30.04, 30. 05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37. 07 or 38.08 by reason of being put up in measured doses or for retail sale, are to be classified in those headings notwithstanding that they could also fall in some other heading of the Nomenclature. While reading this Note, we cannot forget the words in the bracket and which are "other than those described in heading 28.43 to 28.46 or 28.52". Here also, exception is made to goods falling in Heading 28.44.

Therefore, even if the compounds of radioactive isotopes may have uses in medicine, they fall in Heading 2844 only. We very determinedly feel that we need not enter into any discussion or any case law as to what would be a medicament and the properties thereof. 18F-FDG is a radioactive compound (Essentials of Inorganic Chemistry: For Students of Pharmacy, Pharmaceutical Sciences and Medicinal Chemistry by KATJA A. STROHFELDT - Chapter 10 - Radioactive Compounds and Their Clinical Application) and we are guided by the Notes which unambiguously make it clear that –

- Heading 2844 covers radioactive isotopes and their compounds. 18F-FDG being a compound of the radioisotope 18F, it would fall in this Heading 2844.
- All radioactive chemical elements and radioactive isotopes, and compounds of such elements and isotopes (whether inorganic or organic, and whether or not chemically defined), are classified under heading 28.44, even though they could also fall under some other heading of the Nomenclature.

The Tariff item 28444000 reads "**Radioactive elements and isotopes and compounds other than those of sub-heading 2844 10, 2844 20 or 2844 30; alloys, dispersions (including cermets), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues**". Hence, the impugned product would fall in the aforesaid Tariff item.

The applicant has placed an argument that medicaments have been consciously place in Chapter 30 of the Tariff and hence, the same principle should be followed in the case of the instant product. The applicant has also put forth a point that certain other supplier is classifying the impugned product as falling in Chapter 30 (Heading 30.06). With regard to this, we feel that it would have to be appreciated that classification is based on the applicable provisions and not on treatment by suppliers of similar goods. In the present proceedings, we remain unaffected by any mis-classification. For the present, we are convinced in our view that the impugned product merits classification in Heading 2844.

In view of the deliberations held hereinabove, we answer the questions thus -

Question 1

Whether the product 'Fludeoxyglucose' or 'FDG' can be classifiable under Chapter 3006 3000 of the Central Excise Tariff Act, 1985?

The product 'Fludeoxyglucose' or 'FDG' is not classifiable under Chapter 3006 3000 of the Central Excise Tariff Act, 1985 or the Customs Tariff Act, 1975 (51 of 1975).

Question 2

Whether chemicals used as pharmaceuticals that are inorganic or/ and of organic nature shall merit classification only under Chapter 28 & 29 and not under Chapter 30 which has been specifically carved out for chemical pharmaceuticals by makers of law?

It needs to be observed herein that the classification of every product is distinct. A product is to be classified as per the Tariff, Rules of interpretation and other provisions in respect of classification as applicable. The question is of a very general nature and is not for classification of any specific product. In view thereof, this question cannot be entertained under the provisions of section 98 of the GST Act.

05. In view of the extensive deliberations as held hereinabove, we pass an order as follows :

ORDER

(under section 98 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017)

NO.GST-ARA-02/2017/B- 06 **Mumbai, dt.** २१/०२/२०१८

For reasons as discussed in the body of the order, the questions, as posed by Nueclear Healthcare Limited having GSTIN 27AADCN5392G1Z9, are answered thus –

Q.1 Whether the product 'Fludeoxyglucose' or 'FDG' can be classifiable under Chapter 3006 3000 of the Central Excise Tariff Act, 1985?

A.1 The question is answered in the negative.

Q.2 Whether chemicals used as pharmaceuticals that are inorganic or/ and of organic nature shall merit classification only under Chapter 28 & 29 and not under Chapter 30 which has been specifically carved out for chemical pharmaceuticals by makers of law?

A.2 The question cannot be entertained under the provisions of section 98 of the GST Act.

CHAIRMAN, ADVANCE RULING AUTHORITY MAHARASHTRA STATE, MUMBAI

PLACE - Mumbai

DATE - २१/०२/२०१८

—sd— —sd—

B. V. BORHADE **PANKAJ KUMAR**

(MEMBER) **(MEMBER)**

Copy to:-

1. The applicant
2. The concerned Central / State officer
3. The Commissioner of State Tax, Maharashtra State, Mumbai
3. The Jurisdictional Commissioner of Central Tax

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MAHARASHTRA STATE, MUMBAI