INER-F1237 **INER-F1237**

出國報告（出國類別：其他）

赴泰國參加泰國核醫學會 Mid-Year Academic meeting 及參訪 Rajavithi 及 Siriraj 醫院核醫科出國報告

服務機關：核能研究所
姓名職稱：廖美秀　研究員
派赴國家：泰國
出國期間：106 年 12 月 13 日~106 年 12 月 17 日
報告日期：107 年 2 月 5 日

摘　要

本次公差主要是赴泰國參加泰國核醫學會 Mid-Year Academic meeting，由核能研究所同位素應用組廖美秀副組長出席會議演講，介紹核能研究所核醫藥物之研究與發展現況，推廣本所研發成果，並參訪位於泰國曼谷之 Rajavithi 醫院及 Siriraj 醫院核醫科，收集泰國核醫臨床應用及發展趨勢資訊。公差期間自 106 年 12 月 13 日至 12 月 17 日止，共計 5 天。

藉由本次公差，使台灣與泰國互相了解雙方之核子醫學領域發展現況，並建立雙方交流合作之連繫管道，作為未來拓展東南亞市場推動方向之參考。

目　　次

（頁碼）

一、目的

本次公差主要是赴泰國參加泰國核醫學會 Mid-Year Academic meeting，由核能研究所同位素應用組廖美秀副組長出席會議演講，介紹核能研究所核醫藥物之研究與發展現況，推廣本所研發成果，泰國核醫學會另也邀請台北榮民總醫院核子醫學部黃文盛主任於會議演講，介紹台北榮民總醫院核醫藥物發展；本次公差除了出席泰國核醫學會年會於會議演講，並參訪位於泰國曼谷之 Rajavithi 醫院及 Siriraj 醫院核醫科，收集泰國核醫臨床應用及發展趨勢資訊。公差期間自 106 年 12 月 13 日至 12 月 17 日止，共計 5 天。

藉由本次公差，使台灣與泰國互相了解雙方之核子醫學領域發展現況，並建立雙方交流合作之連繫管道，作為未來拓展東南亞市場推動方向之參考。

二、過程

月	日	星期	地點	工 作 紀 要
12	13	三	桃園→曼谷	去程及參訪 Rajavithi、Siriraj 醫院核醫科
	14	四	曼谷→芭達雅	路程及參加泰國核醫學會 Mid-Year Academic meeting 演講
	15	五	芭達雅	參加泰國核醫學會 Mid-Year Academic meeting
	16	六	芭達雅→曼谷	路程及整理資料
	17	日	曼谷→桃園	回程

三、心　得

本次公差主要是赴泰國參加泰國核醫學會 Mid-Year Academic meeting，由核能研究所同位素應用組廖美秀副組長出席會議演講，此會議係於泰國芭達雅的 Long Beach Garden Hotel and Spa 二樓會議廳舉行，由泰國核醫學會主辦，會議時間為 106 年 12 月 14-15 日兩天，總與會人數約 150 餘人，成員為泰國核醫學會會員，包含醫師、放射師、藥師、技術人員等，此會議第一天首先即安排台北榮民總醫院核子醫學部黃文盛主任及核能研究所同位素應用組廖美秀副組長演講，演講題目分別為 Development of Nuclear medicine in Taipei Veterans General Hospital 及 The Research and Development of Nuclear Medicine in INER，介紹台北榮民總醫院臨床核醫及核能研究所核醫藥物之發展，議程如附錄一。

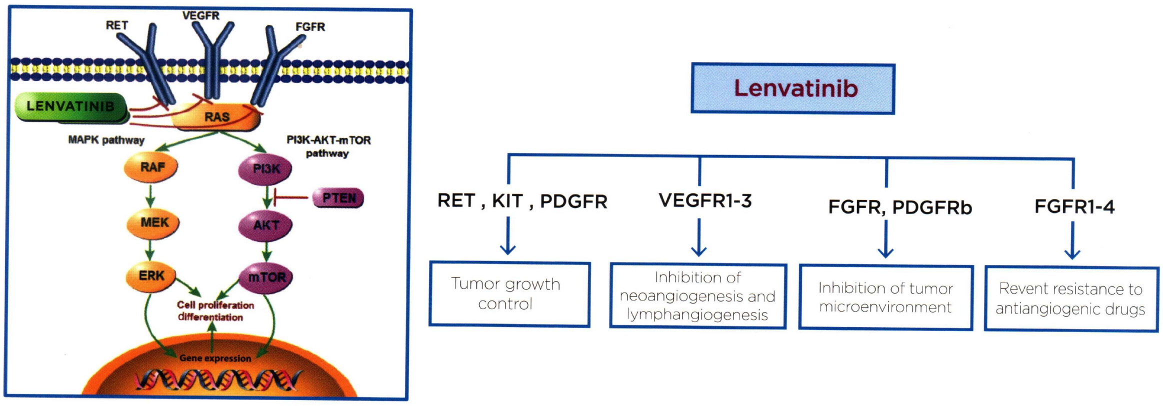
會場並有核子醫學儀器、藥物及輻防器材等廠商及單位進行展示，包括 GE Healthcare、Global Medical Solutions(GMS)、Eisai、BqSv、Bayer HealthCare、Thailand Institute of Nuclear Technology(TINT)等等 10 餘家廠商，各廠商展示重點說明如下:

(一)Global Medical Solutions(GMS) 泰國分公司展示攤位於會場入口處，占地最大，並以核能研究所技轉成功之多巴胺轉運體造影劑(TRODAT-1 KIT)為主軸進行展示，其宣傳文宣如附錄二，該分公司經理 Gem Gallegos 對於利用鎝-99m TRODAT-1 及碘-123 IBZM 合併造影，分別利用多巴胺轉運體(Dopamine transporters, DATs)及多巴胺受體(Dopamine receptor)核醫影像來協助鑑別各種巴金森氏症候群非常有興趣;另表示 TRODAT-1 目前在泰國的推廣上，因他們的核醫藥局配製後，須在 4 小時內運送至醫院使用，對於泰國目前的核醫醫院分佈，執行面上會希望標誌後產品能有更長的經時安定性，以利有足夠的運送時間，此意見可供未來本所產品開發方向之參考。

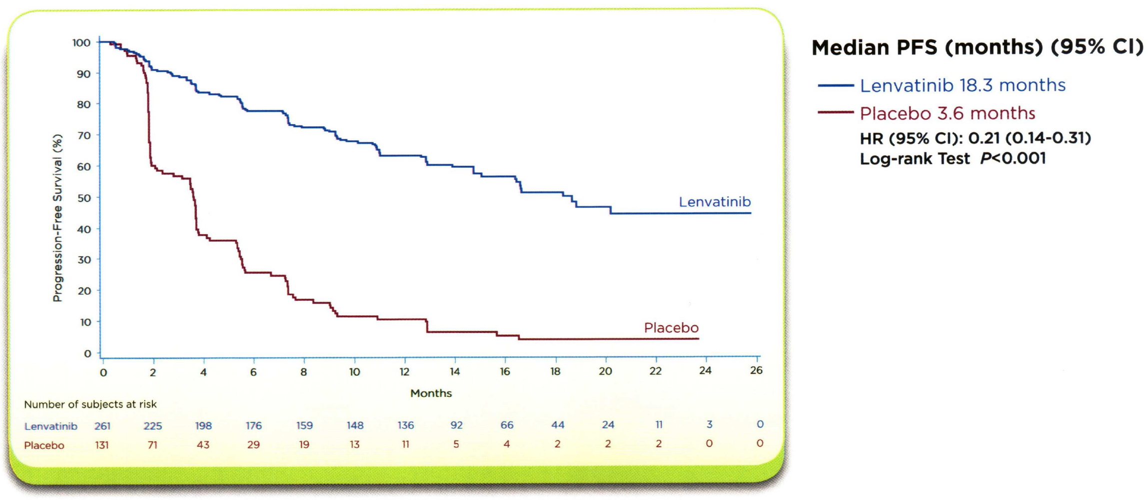
(二)GE Healthcare 公司展示宣傳新儀器 Discovery NM/CT 670 CZT，此為第一台利用 CZT 技術的 SPECT/CT 商用造影儀器， CZT(Cadmium Zink Telluride, CdZnTe)是可將 X 射線或加馬射線的光子直接轉換成電子的半導體，未來將成為核醫造影儀器的主要組件。Discovery NM/CT 670 CZT 可改善系統空間解析力由 4.3 mm 提升至 2.8 mm、改善 40%以上的 contrast-to-noise ratio，大大提高病灶偵測能力及影像品質，並可降低注射藥物劑量及縮短造影時間提升病患舒適性。

(三)Eisai 公司展示宣傳核醫治療藥物 LENVIMA™(lenvatinib)膠囊，lenvatinib 是一個口服多標靶性的酪胺酸激酶抑制劑(tyrosine kinase inhibitor, TKI)，作用在 VEGFRs 1-3(Vascular Endothelial Growth Factors, 血管內皮生長因子), FGFRs 1-4(Fibroblast Growth Factor Receptors 1-4), PDGFR α(Platelet-derived Growth Factor Receptor, 血小板衍生生長因子), RET(Rearranged during transfection tyrosine kinase receptor)及 KIT 訊息網絡，作用機制如圖一，透過激酶訊息瀑布(Kinase signaling cascade)可控制腫瘤生長、抑制血管新生(neoangiogenesis)及淋巴管新生(lymphangiogenesis) 、抑制腫瘤微環境(tumor microenvironment)等。Dr. Martin Schlumberger 等人於 2015 年發表在 The New England Journal of Medicine 有關 lenvatinib 在對放射性碘-131 治療無效之進行性，且為局部晚期或轉移性之分化型甲狀腺癌(Differentiated thyroid cancer, DTC)患者的臨床三期研究顯示，納入 392 位甲狀腺癌受試者，其中 261 位受試者每天口服 24mg lenvatinib，另 131 位受試者則服用安慰劑，完成 8 天的療程後，結果顯示 lenvatinib 治療組的平均存活期是 18.3 個月，而服用安慰劑的對照組為 3.6 個月，兩組無病變存活率(progression free survival)比較如圖二，lenvatinib 治療組的緩解率(response rate)為 64.8%，其中有 4 位受試者完成緩解，165 位受試者部份緩解，而對照

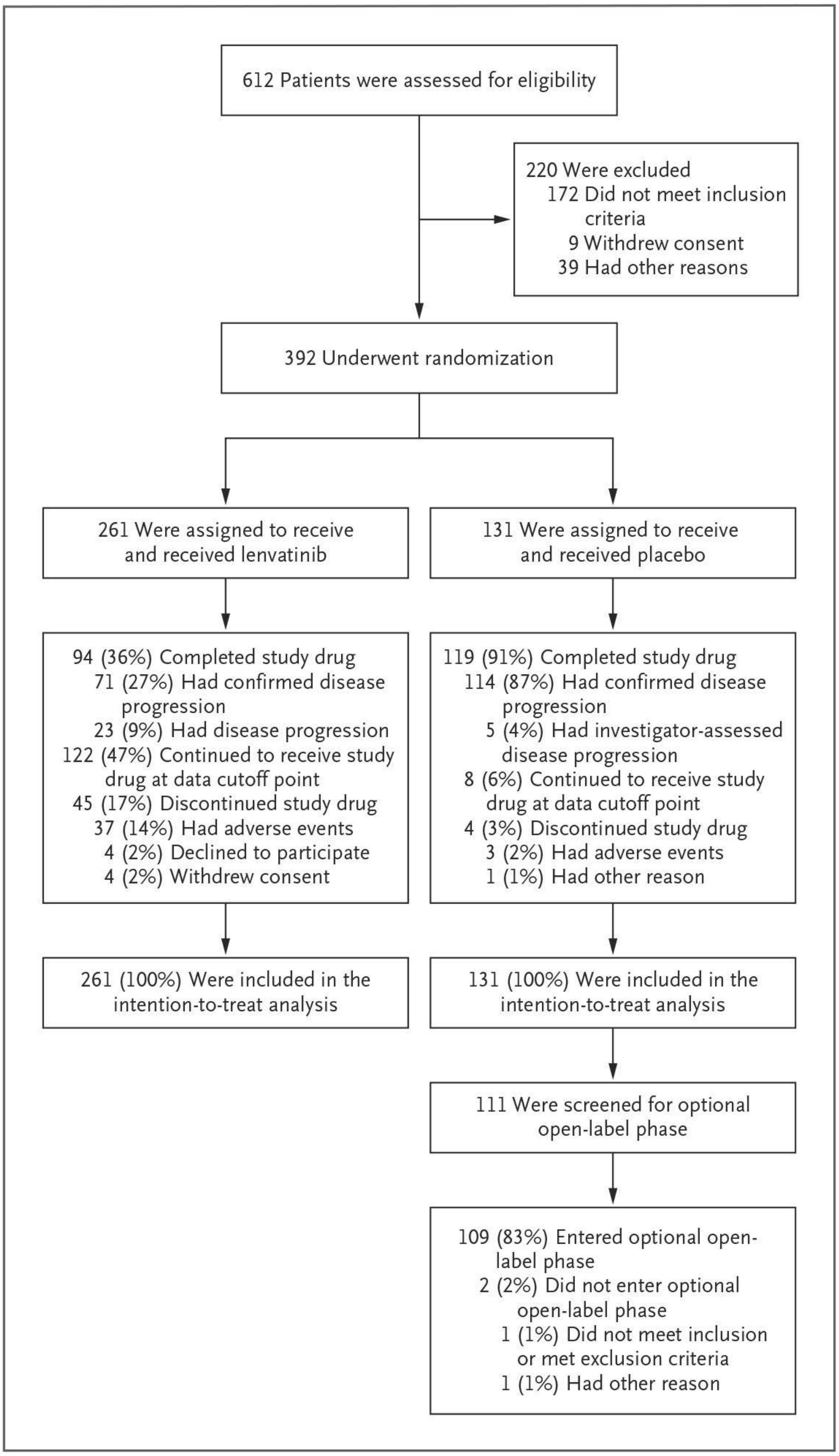
組的緩解率僅 1.5%，臨床試驗的納入及治療設計如圖三，由數據可見，lenvatinib 對於 I-131 治療不佳的甲狀腺癌患者具有意義地提升其平均存活期及緩解率。



圖一、lenvatinib 作用機制

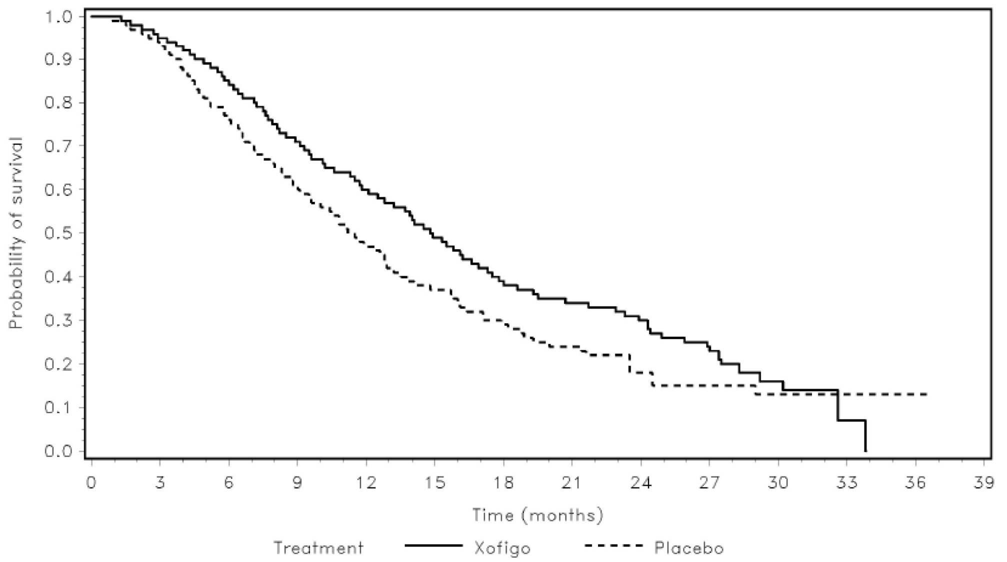


圖二、lenvatinib 第三期臨床試驗存活率比較



圖三、lenvatinib 第三期臨床試驗受試者之納入及治療設計

(四)Bayer HealthCare 公司展示宣傳核醫治療藥物 Xofigo® (Radium-223 dichloride)，90%前列腺癌患者會擴散至骨骼，而 Radium-223 與鈣相似，故會被骨骼所吸收，利用 Radium-223 釋放出的α粒子殺死癌細胞，並且對周圍的正常細胞傷害小，由第三期臨床試驗結果顯示 Radium-223 dichloride 治療組的存活期是 14.9 個月，而服用安慰劑的對照組為 13.3 個月，可延長 30%以上的存活期，兩組整體存活率(overall survival)比較如圖四。



Number of patients at risk

Xofigo	614	578	504	369	277	178	105	60	41	18	7	1	0	0
Placebo	307	288	228	157	104	67	39	24	14	7	4	2	1	0

圖四、Radium-223 dichloride 第三期臨床試驗存活率比較

(五)Thailand Institute of Nuclear Technology(TINT)是隸屬於泰國政府科技部的機構，與核能研究所(INER)相似，主要任務是負責國家的核子科技研發，並且提供核子科技的技轉及服務，其機構簡介如附錄三，主要組織編制及服務簡要說明如下:

1. 核子技術服務中心(Nuclear Technology Service Center):負責工業用非破壞性檢測、人員輻射曝露監測、輻射儀表校正、進出口貨品放射性監測、元素分析及放射性物質運送包件檢查等。
2. 輻射照射中心(Irradiation Center):負責食品及農產品的輻射照射，照射品項包括香料、藥草、水果、海鮮等，其中提供芒果、鳳梨等六種水果的照射服務更協助出口美國，並設置有 Microorganism Analysis 提供各種產品的微生物、酵母菌及黴菌等檢驗服務。
3. 放射性廢棄物管制中心(Radioactive Waste Management Center) :負責泰國境內公私立部門之放射性廢棄物處理技術之研究及提供相關訓練，並設置有 Water Testing Laboratories 提供放射性廢水之檢測服務。
4. 寶石輻射照射中心(Gems Irradiation Center) :提供輻射照射服務進行寶石變色以增加其市場價值，提供的照射方式有鈷-60 加馬照射、20-MeV, 10 kW 電子束加速器(e-beam accelerator)及核反應器(Nuclear reactor)的中子照射。
5. 放射性同位素中心(Radioisotope Center):負責生產放射性同位素、放射性標誌化合物、鎝-99m 核醫藥物、密封射源等，提供醫學、農業、研發及教育使用。目前提供泰國境內 25 家公私立醫院使用，每年服務 30 萬人次，可節省外匯至少 2,300 萬泰幣。主要提供的放射性同位素為 I-131、Sm-153、P-32，放射性標誌化合物為 I-131-Hippuran、I-131-MIBG、Sm-153-EDTMP、Sm-153-Hydroxyapatite、Ga-68-DOTATATE，而鎝-99m 核醫藥物則有 MDP、DTPA、MAA、DMSA、DMSA(V)、Phytate、DISIDA、Stannous、MAG3、EC、ECD、Hynic-TOC、Ciprofloxacin 等。

為加強雙方合作交流，核能研究所與泰國核醫學會於 106 年 11 月在台灣簽署合作備忘錄(MOU)，本次公差也將雙方完成簽署之 MOU 正式交付泰國核醫學會現任理事長 Dr. Yuthana Saengsuda，並參訪位於泰國曼谷之 Rajavithi 醫院及 Siriraj 醫院核醫科，收集泰國核醫臨床應用及發展趨勢資訊。

本次參訪曼谷兩家醫院所主要拜會人員名單如下列:

單位	部門	職稱	姓名
Rajavithi Hospital	Department of Pathology	Chief	Thiti Kuakpaetoon
Rajavithi Hospital	Division of Nuclear Medicine	Chief	Yuthana Saengsuda
Nuclear Medicine Society of Thailand	-	President	
Rajavithi Hospital	Division of Nuclear Medicine	技術主管	Sureerat Saengsuda
Siriraj Hospital	Division of International Relations	Chief	Prapat Wanitpongpan
Siriraj Hospital	Division of Nuclear Medicine	Doctor	Benjapa Khiewvan

本次公差與台北榮民總醫院核子醫學部黃文盛主任共同拜會 Rajavithi 醫院及 Siriraj 醫院，於 Rajavithi 醫院參與台北榮民總醫院與 Rajavithi 醫院雙方簽署合作備忘錄(MOU)之儀式，Rajavithi 醫院並邀請台北榮民總醫院能安排 5 位醫師於 107 年 2 月 21-23 日出席 Rajavithi 醫院的第 29 屆學術研討年會，希望台灣能安排癌症手術的最新技術進行分享；而 Siriraj 醫院國際關係部主任 Dr. Prapat Wanitpongpan 也表示很希望與台灣醫院及研究機構建立合作交流關係，並提供其合作備忘錄(MOU)之範本，如附錄四，期能有機會與台灣相關機構簽署合作，促進雙方的醫療技術及研究人員交流的機會。

泰國核醫學會目前有 290 位會員，其中 78 位醫師，其餘則為物理師、技術人員、藥師、放射化學人員及護士等，固定在每年 3 月及 10-12 月舉

辦年會，醫院主要分佈在曼谷及清邁等大城市。泰國 2015 年國內生產總值（Gross Domestic Product，GDP)為 12.06 兆泰幣，全國每年醫療支出 5185.8 億泰幣，占 GDP 的 4.3%，而核醫每年總支出 4,970 萬泰幣則占全國醫療支出的 0.1%，相較於台灣於 2013 年核醫全年總支出 24.61 億新台幣，占全國每年醫療支出的 0.48%，泰國人口約 6,700 萬，目前全國僅有 11 台 PET/CT，平均每 627 萬人口使用 1 台，可見泰國核醫仍有很大的成長空間，目前 PET/CT 泰國政府有支付保險費用的檢驗項目為非小細胞肺癌及大腸癌疑似復發二項，預計 2018 年會再增加給付三項，包括所有類型的肺癌、直腸癌及淋巴癌。

泰國設有核醫科的醫院共有 29 家，其中公立醫院有 9 家為大學附設醫院、8 家一般醫院、5 家癌症專科醫院，共 22 家，而 7 家私立醫院則為 4 家一般醫院、3 家癌症專科醫院;而其位置分佈為曼谷 16 家，占 55%，其餘中部 2 家、北部 3 家、南部 2 家、東北 4 家及東部 2 家。4 家醫院設置有小型迴旋加速器，包括 Chulabhorn hospital、Wattanosot hospital、Siriraj hospital、Chiangmal hospital，其它重要設備數量如表一。

表一、泰國核醫重要設備數量

設備名稱	數量	設備名稱	數量
Gamma camera	12	Cardiac SPECT	2
Gamma probe	12	PET/CT	11
Rectilinear scanner	6	PEM	1
Static gamma detector	9	Dose calibrator	10
Planar gamma camera	1	Survey meter	7
SPECT gamma camera	27	Bone densitometer	10
SPECT/CT gamma camera	10	Contamination Survey meter	2

2015 年泰國核醫共完成 59,455 人次診斷造影(台灣 2013 年約 36 萬人次)，其中前 5 大檢查項目占 87.9%，分別為骨骼造影 47.5%、I-131 全身掃

瞄 12.5%、心臟造影(Cardiac scan) 11.3%、PET oncology 9.3%、甲狀腺掃瞄 7.5%；而核醫治療完成 2,338 人次，其中甲狀腺癌占 28.8%、甲狀腺機能亢進(Hyperthyroidism) 占 70.2%、骨轉移治療為 41 人次、其它 Y-90 microspheres 及 I-131-MIBG 等則為 61 人次；在 8 家醫院完成 5,882 人次 PET 造影(台灣 2013 年約 23 萬人次)，其中 5,529 人次(94%)為癌症造影，腦部造影為 161 人次(2.7%)，骨骼造影為 181 人次(3.1%)，另有心臟及感染造影分為 2 及 9 人次。

核醫藥物的供應來源依其類別分為鎝-99m 標誌單一劑量(unit dose)、非鎝-99m 標誌核醫藥物、治療用核醫藥物及凍晶製劑，分別列於表二-五。

表二、鎝-99m 標誌單一劑量(unit dose)核醫藥物及其供應者

核醫藥物	供應者	
	TINT	GMS
Tc-99m-DISIDA	○	○
Tc-99m-DTPA	○	○
Tc-99m-ECD	○	○
Tc-99m-Hynic-TOC	○	×
Tc-99m-MAA	○	○
Tc-99m-MAG3	○	○
Tc -99m-MDP	○	○
Tc -99m-MIBI	○	○
Tc-99m-Sulfur Colloid	×	○
Tc-99m 過鎝酸鈉溶液	○	○
Tc-99m-Phytate	○	○

* TINT: Thailand Institute of Nuclear Technology

GMS: Global Medical Solutions

表三、非鎝-99m 標誌核醫藥物及其供應者

核醫藥物	供應者			
	TINT	GMS	Wattanosoth Hospital	Chulabhorn Hospital
F-18 FDG	×	×	○	○
C-11 PiB (Amyloid)	×	×	○	○
F-18 THK5351 (Tau)	×	×	×	○
F-18 FDOPA	×	×	○	○
F-18 NaF	×	×	○	○
Ga-67 citrate	×	○	×	×
Ga-68 DOTATATE	○	×	×	×
Ga-68 PSMA	×	×	×	○
I-131 Diagnosis Capsule	○	○	×	×
I-131 MIBG for Diagnosis	○	×	×	×
I-131 Hippurate	○	×	×	×
In-111 OctreoScan	×	○	×	×
Tl-201 chloride	×	○	×	×

表四、治療用核醫藥物及其供應者

核醫藥物	供應者		
	TINT	GMS	Biogenetech
I-131 Therapeutic Capsule	○	○	×
I-131 MIBG for Treatment	○	×	×
Sm-153 EDTMP	○	○	×
Sr-89 chloride	×	○	○
Y-90 microsphere	×	○	×
Y-90 citrate colloid	×	○	○
Ra-223 chloride	×	○	×

表五、凍晶製劑類核醫藥物及其供應者

核醫藥物	供應者			
	TINT	GMS	Biogenetech	In-House
DISIDA	○	×	×	×
DMSA	○	×	×	×
DMSA(V)	○	×	×	○
DTPA	○	×	×	○
EC	○	×	×	×
ECD	○	×	×	×
HSA	×	○	×	○
Hynic-TOC	○	×	×	×
Leukocyte	×	○	×	×
MAA	○	×	×	×
MAG3	○	×	×	×
MDP	○	○	○	○
MIBI	○	×	○	×
Rhenium Sulfide	×	×	○	×
Phytate	○	×	×	×
PYP	×	○	×	○
Stannous	○	○	×	○

以 Chulabhorn hospital 為例來看，該院核醫科配置有 3 位醫師，並具有迴施加速器、PET/CT、SPECT/CT 各 1 台，可生產 F-18-FDG、F-18-FDOPA、C-11-choline、C-11PiB、C-11Erlotinib、F-18-THK-5351 等，於 2015 年及 2016 年分別生產 1,874 及 2,448 劑藥物，1 年間成長 30.6%，PET/CT 造影人次於 2016 年的 610 人次至 2017 年增加至 1,297 人次，增加超過 100%，由此具指標性醫院的數據可見泰國核醫市場正處於開始成長的階段。

本次公差，收穫頗豐，由本次會議演講及參訪其醫療機構，使台灣與泰國互相了解雙方之核子醫學領域發展現況，增加未來雙方合作交流的機會，期對兩國在醫藥相關計畫規劃及合作研發方向皆能有所助益，並拓展國內醫藥人員視野與建立雙方交流合作之連繫管道，作為未來拓展東南亞市場推動方向之參考。

四、建　議　事　項

本次公差赴赴泰國參加泰國核醫學會 Mid-Year Academic meeting，由核能研究所同位素應用組廖美秀副組長出席會議演講，介紹核能研究所核醫藥物之研究與發展現況，推廣本所研發成果，並參訪位於泰國曼谷之 Rajavithi 醫院及 Siriraj 醫院核醫科，收集泰國核醫臨床應用及發展趨勢資訊。

依此次公差結果，對國內發展有如下之建議：

(一) 台灣現有醫療及研究水準相較於泰國仍較先進，惟泰國目前整體係呈現逐步進步中，在此過程中，台灣仍可運用自身優勢與泰國建立合作交流之關係，強化雙方互信及友誼，對於台灣未來發展必能有所幫助。

(二) 泰國人口約有台灣 3 倍，有一定的內需市場，且因其人口分佈集中於大城市，隨著國家經濟成長，其國人的醫療需求也必會隨之成長，故台灣應在泰國尚在成長進程中，即提早佈局，可透過學術會議、臨床及研究訓練及交換學生等方式長期穩定交流，建立雙方合作互動，藉以穩固雙方關係，才能從中找到機會。

(三) 透過本次公差實際瞭解泰國核醫市場現況，可發現因其人口地域分佈及醫事法規環境而與台灣有所差異，泰國政府對核醫藥物使用的管制有較高的自由度，因此，其臨床醫師對於使用到各項世界最新的核醫藥物較台灣來得容易，對本所研發之核醫藥物推廣應用極具參考價值，可納入本所未來研發方向之參酌;若核能研究所的核醫藥物開發未來希能行銷海外，對於各個國家的國情及市場必須充分掌握，才能事半功倍。

(四) 應多參與國外各醫學學會演講及參訪其醫療研究機構，可促進彼此瞭解，增加未來雙方合作交流的機會，做為本所研提新計畫時之參酌。

五、附　錄

附錄一、泰國核醫學會 Mid-Year Academic meeting 議程

Final_Program_14-15 Dec 2017

Mid-Year Academic Meeting of the Society of Nuclear Medicine of Thailand

14 – 15 December 2017

Long Beach Garden Hotel and Spa, Pattaya, Thailand

14 December 2017		
13.00 – 13.15	**Opening Ceremony**	Dr. Yuthana Saengsuda President of NMST
13.15 – 13.45	**Developments of NM in Taipei Veterans General Hospital**	Wen-Sheng Huang Department of Nuclear Medicine Taipei Veterans General Hospital, Taiwan (R.O.C.)
13.45 – 14.15	**The Research and Development of Nuclear Medicine in Institute of Nuclear Energy Research**	Dr. Mei-Hsiu (Michelle) Liao, PhD Associate Scientist/Deputy Director, Division of Isotope Application Taiwan (R.O.C.)
14.15 – 14.45	**Recent advances in multimodal molecular tomography**	Mr. Staf C. van Cauter M.Sc., MBA Executive Director MILabs B.V., Utrecht, the Netherlands
14.45 – 15.00	*Coffee break*	
15.00 – 15.30	**Treatment of hepatocellular carcinoma with Y-90 SIRT**	อ.พญ.อจลญา เตยะธิติ รพ. ศิริราช
15.30 – 16.00	**เปิดโลกทัศน์ใหม่หมอนิวเคลียร์: ผู้หญิงเลี้ยวซ้าย ผู้ชายเลี้ยวขวา**	อ.พญ.นันทพร วงศ์สุรวัฒน์ ม.ขอนแก่น อ.นพ.ธฤต แตระกุล รพ.ราชวิถี
16.00 – 16.30	**Practical radiation protection in therapeutic nuclear medicine: Important risks and key considerations**	ดร.กฤศณัฏฐ์ เชื่อมสามัคคี รพ.รามาธิบดี
16.30 – 17.00	*"Radiopharmacy gathering" ขอเชิญผู้ที่ทำงานเกี่ยวกับ Radiopharmacy จากสถาบันต่าง ๆ เสวนาร่วมกันหลังจากจบหัวข้อประชุมสุดท้ายของวันนี้*	
15 December 2017		
9.00 – 9.30	**PET-CT: Experience at Mount Sinai Hospital**	ผศ.พญ.ดนึงนิจ ธรรมนิรัต รพ.รามาธิบดี
9.30 – 10.00	**PET-CT: Egyptian case series**	Assoc. Prof. Dr. Mohamed Houseni National Liver Institute, Egypt
10.00 – 10.30	**Clinical experience with CZT Technology: The future of SPECT/CT**	Prof.Ora Israel The Director of Nuclear Medicine/PET at Rambam, Israel
10.30 – 10.45	*Coffee break*	
10.45 – 11.45	**"Lenvatinib" The new targeted multityrosine kinase inhibitors for radioactive iodine refractory differentiated thyroid cancer: Thai experiences**	ผศ.นพ.สืบพงศ์ ธนสารวิมล รพ.จุฬาฯ
11.45 – 12.00	**Closing ceremony**	Dr. Yuthana Saengsuda President of NMST

附錄二、Global Medical Solutions(GMS) 泰國分公司展示攤位之多巴胺轉運體造影劑(TRODAT-1 KIT)宣傳文宣

^{99m}Tc-TRODAT-1: Imaging Approaches to Parkinson's Disease

Background:

^{99m}Tc-TRODAT-1, which binds to the dopamine transporter (DAT) located on the presynaptic nerve endings in striatum, has been reported by Dr. Hank F. Kung[1] as a SPECT imaging agent for the diagnosing and monitoring of the progression of Parkinson's Disease (PD). It was first developed in a commercially available form by the Institute of Nuclear Energy Research (INER) of Taiwan. The product was granted marketing approval by TFDA (Taiwan Food and Drug Administration) in 2005. In 2015, Global Medical Solution (GMS) Taiwan has acquired the ownership of this clinically proven product from INER. Ever since its launch a decade ago, ^{99m}Tc-TRODAT-1 has been commonly used in many countries (Taiwan, India, Brazil, etc....) as an adjunct to other diagnostic modalities of PD. Today, more than 10,000 scans are performed annually worldwide with this product.

Indication:

Imaging of dopamine transporters located in the dopaminergic presynaptic neuron terminals in the striatum

Reported Clinical Application:

1. Clinically uncertain Parkinsonian Syndromes[2,3.]
2. To differentiate Essential Tremor from Parkinsonian Syndromes related to idiopathic Parkinson's Disease, Multiple System Atrophy and Progressive Supranuclear Palsy[4]

Dosage & Administration:

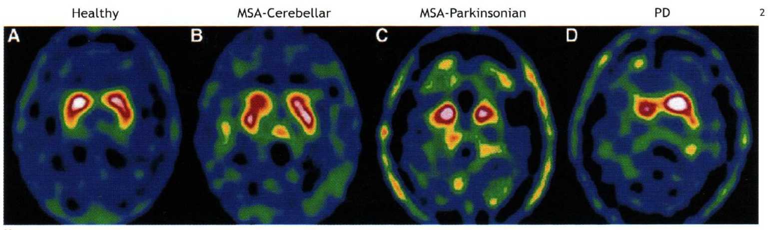
1. Each 10 ml-vial contains 126 μg TRODAT-1 · 3HCl
2. The recommended dose range for I.V. administration of Tc-99m-TRODAT-1 in a single dose to be employed in the average patient (70 kg) dose is 814~1,036 MBq (22~28 mCi).
3. SPECT imaging should be performed after 3~4 hours post-administration.

Contraindication & Adverse Reaction:

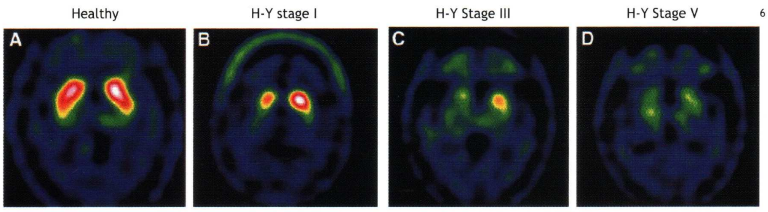
1. Contraindications are non known
2. Adverse reactions have been reported occasionally, includes dizziness, back pain, hypertension and paresthesia.

Clinical Imaging:

During the past decades, several clinical studies have reported that ^{99m}Tc-TRODAT-1 is a safe, convenient, and reliable imaging agent for measuring DAT. It is used to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS)[2.3] The agent is also useful to help differentiate essential tremor from tremor due to Parkinsonian syndromes (Idiopathic Parkinson's disease, multisystem atrophy and vascular parkinsonism)[4] In addition, ^{99m}Tc-TRODAT-1 may be able to detect the early stage of Parkinson's disease[5] and measure the disease progression.[6,7]



^{99m}Tc -TRODAT-1 SPEC images of 4 similarly aged individuals



(A)Healthy volunteer (B)H-Y stage I with left side tremor and bradykinesia (C)H-Y stage III with bilateral bradykinesia, dominant in the left side (D)H-Y stage V with severe bilateral akinesia

Storage

^{99m}Tc-TRODAT-1 should be stored in a refrigerator (2~8 ℃) upon receiving and protected from light until use.The reconstituted preparation should be stored at room temperature and must be used within 4 hours after preparation. The shelf life is 6 months (2~8℃).

Package

5 vials / Box

Reference

1.Kung MP et al. Eur J Nucl Med 1997; 24:372-380
2.Lu CS et al. J Nucl Med 2004; 45(1):49-55
3.Tzen KY et al. J Nucl Med 2001; 42(3): 408-413
4.Fallahi B et al. Ann Nucl Med 2016; 30(2):153-62
5.Chou KL et al. Park Relat Disord 2004; 10: 375-379
6.Weng YH et al. J Nucl Med 2004; 45(3):393-401
7.Hwang WJ et al. J Nucl Med 2004; 45(2):207-213

Global Medical Solutions Taiwan
11F, 237, Fu-Shing S. Road, Sec. 1, Taipei 10666, Taiwan, R.O.C.
Phone: +886-2-2707-9900
Website: www.gmstw.com.tw
contact: info@gmstw.com.tw


TRODAT-1 Kit
Quality imaging of dopamine transporters
More accessible and more economical
GMS
Global Medical Solutions
The Service Difference

^{99m}Tc-TRODAT-1
Image Protocol

^{99m}Tc-TRODAT-1 SPECT procedure:

A. Imaging acquired parameters:

Using a dual-head SPECT imaging scanner, equipped with a fan-beam collimator or low energy high resolution (LEHR) collimator, and installing a head holder. Patient should be asked to urinate before examination and informed of the examination duration, so that he/she can receive the examination in a comfortable state.

The recommendations for the instrument image parameter are as following:

i. **SPECT scan time point:** 3 or 4 hours after ^{99m}Tc-TRODAT-1 is injected.

ii. **Center of rotation:** The center of rotation should be minimized as much as possible, while providing that patient safety and examination are not compromised. The usual value is approximately 12 to 15 cm. Hospitals should fix this parameter to minimize human error.

iii. **Matrix size:** 128 x 128

iv. **Step-and-shoot imaging acquisition:** Each detector head will rotate at 360° and each detector head collects 120 projections. Collect each projection for 20 seconds at each angle. Then the scanning duration is about 45 minutes.

v. **Energy window:** 140 keV ± 10%

vi. **Total counts:** > 5 x 10^6 counts are suggested for image quality

Image Post-Processing:

A. Projection preview:

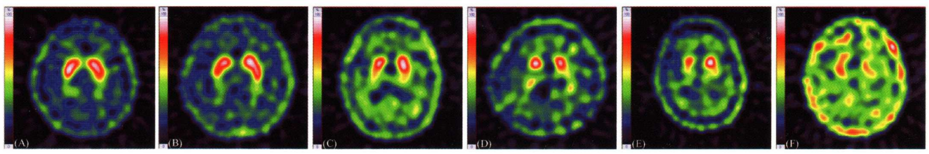
After acquisition, the correct concept for image reconstruction is to first preview unprocessed projection data to evaluate them for the presence of motion or other potential artifacts. During preview, a linogram or sinogram can be used for evaluation to guarantee there are no errors before proceeding with image reconstruction.

B. Attenuation correction:

Attenuation-corrected images facilitate image interpretation and semi-quantitative analysis. Attenuation correction can be achieved through two methods. The first method involves using a penetrating radiation source (e.g., CT, Gd-153) to measure the linear correction coefficient(μ) of the head and subsequently correct the signal strength of attenuated images. The second method involves correction for photon attenuation is the first-order Chang's method. The 0.12/cm is the linear correction coefficient based on the energy spectrum of Tc-99m.

C. Image reconstruction:

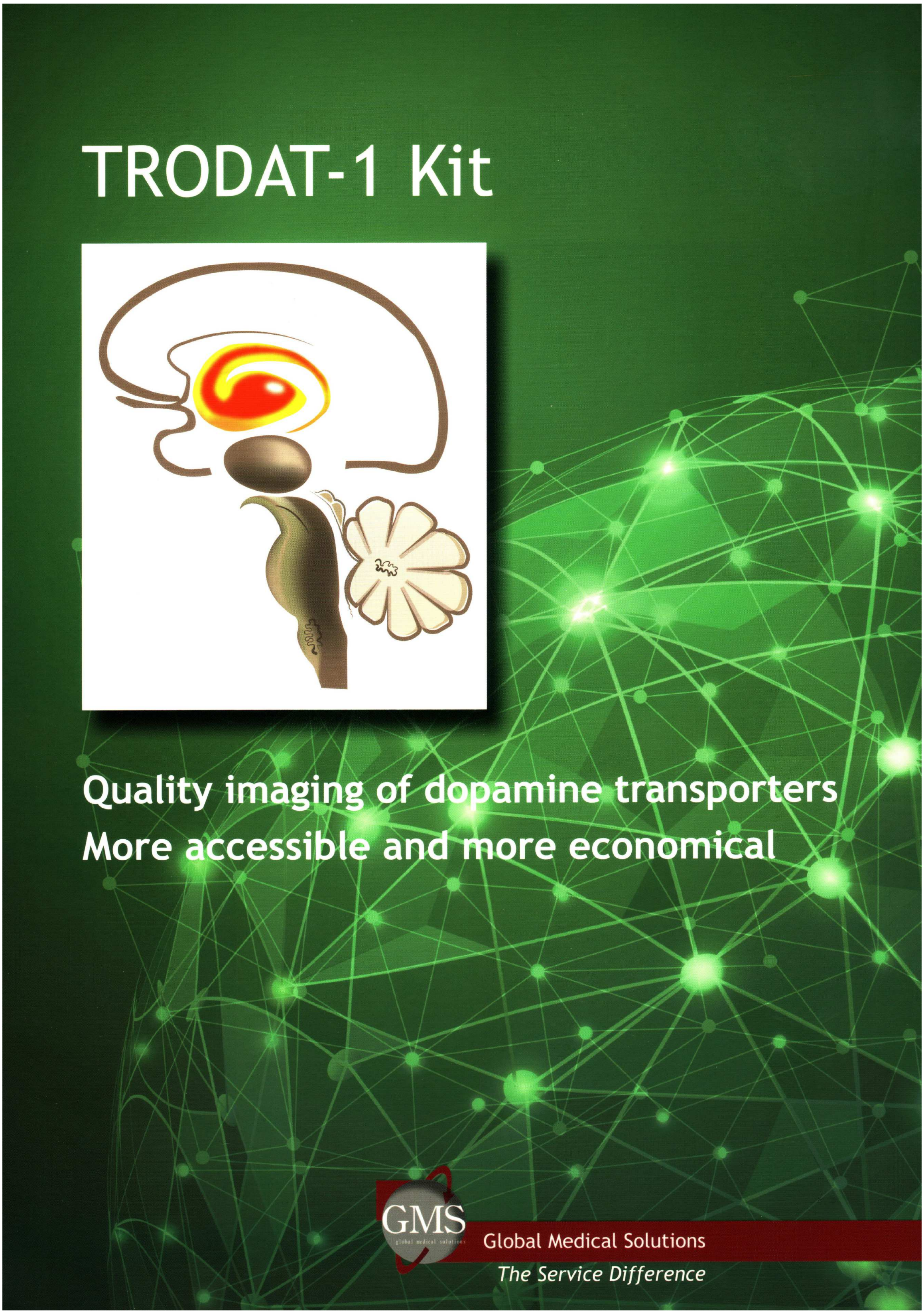
Employ filter back-projection (FBP) for reconstruction, in which a low-pass filter (e.g., Butterworth filter) or band-pass filter (e.g., Metz filter) can be used. The post-image reconstruction quality requirements are closely related to physician interpretation.



Various degrees of PD defined by visual inspection. (A) is normal (B)-(F)are stage I -V, respectively. Reduced uptake in whole striatum can be observed in advanced PD, and asymmetrical uptake in putamen can be found in early stages

Reference: BH Yang, et al. An Nucl Med & Mol Imaging. 2016;29:45-53

Global Medical Solutions Taiwan
11F, 237, Fu-Shing S. Road, Sec. 1, Taipei 10666, Taiwan, R.O.C.
Phone: +886-2-2707-9900
Website: www.gmstw.com.tw
contact: info@gmstw.com.tw


TRODAT-1 Kit
Quality imaging of dopamine transporters
More accessible and more economical
GMS
Global Medical Solutions
The Service Difference

^{99m}Tc-TRODAT-1
Patient Preparation

Before the scan

- Stop drugs which may affect the affinity of TRODAT-1 to Dopamine transporter (DAT). The drug should be withdrawal for at least 5 half lives in order to eliminate most of the drug in the body.
  These drugs includes central nervous stimulant drugs/certain anti-depressant drugs/ certain narcotic analgesics[1,2]

Name of Drug	
Amphetamine	Bupropion or Amfebutamone
Cocaine	Mazindol
Methylametamine	Methylphenidate
Modafinil	Phentermine

- No food restriction
- No need to withdraw Anti-Parkinson Drugs[2]:
  L-dopa, dopamine agonists, MAO-B inhibitor, Amantadine, COMT inhibitors, NMDA receptor antagonists

During the Scan[3]

- The I.V. administration of 1cc of ^{99m}Tc-TRDOAT-1 is usually performed in the nuclear medicine department
- The recommend single dose in the average patient (70kg) is 814~1036 MBq (22~28mCi) in liquid solution
- The SPECT scan start to perform 4 hours after IV administration with scanning time of 40~45 minutes
- During the 4 hours of waiting, the patient is able to drink water
- The adverse effects are rare, and includes dizziness, back pain , hypertension and paresthesia

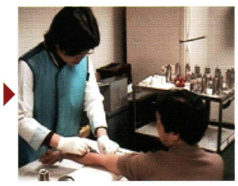
After the Scan

- To minimize the radiation dose to the bladder and other targeted organs, patient should increase fluid intake after the scan.
- Sodium Pertechnetate Tc-99m is excreted in human milk during lactation; therefore, formula feedings should be substituted for breast-feeding for 48 hours following the scan. During this time, breast milk should be expressed at regular intervals and the expressed one should be discarded.
- Patient may need to obtain a letter of TRODAT scan if he/she intends to travel abroad within 5 days after scan.

Precautions

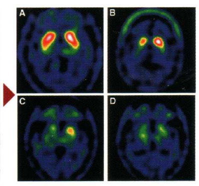
- Animal reproduction studies have not been conducted with ^{99m}Tc-TRDOAT-1. It is also not known whether this drug can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. ^{99m}Tc-TRDOAT-1 should be given to a pregnant woman only if it is clearly needed.

GMS TRODAT-1 kit reconstructed with Sodium Pertechnetate ^{99m}Tc solution



IV admission of 1cc ^{99m}Tc-TRODAT-1

SPECT scan of 40~45 minutes



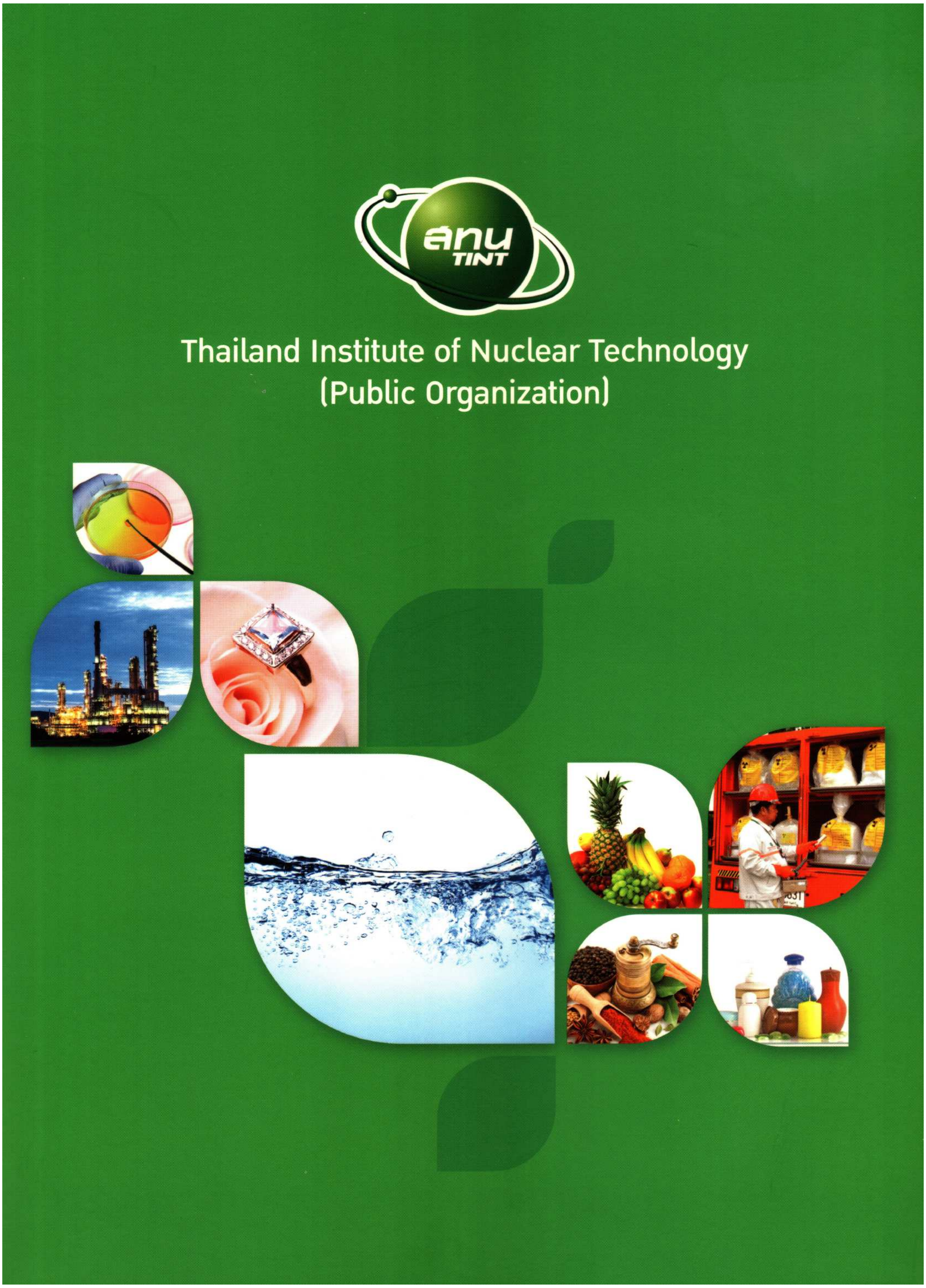
Acquisition of images[4]

Reference

1.Eshleman AJ et al. J Pharmaco Exp Ther 2001; 296(2): 442-449
2.Cummings JL et al. Brain 2011; 134: 3146-3166
3.TRODAT-1 Kit Insert
4.Weng YH et al. JNucl Med 2004; 45(3): 393-401

Global Medical Solutions Taiwan
11F, 237, Fu-Shing S. Road, Sec. 1, Taipei 10666, Taiwan, R.O.C.
Phone: +886-2-2707-9900
Website: www.gmstw.com.tw
contact: info@gmstw.com.tw

附錄三、Thailand Institute of Nuclear Technology(TINT)機構簡介



Thailand Institute of Nuclear Technology (Public Organization)

OUR VISION

To be a leading nuclear solution-based research institute for the Nation

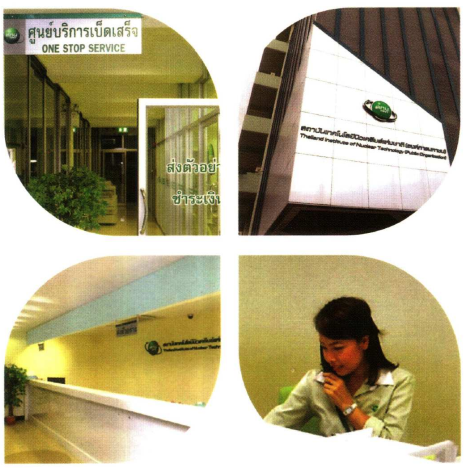
MISSION

- Carry out research and development on nuclear science and technology for the sustainable development of the country
- Transfer technology and provide consultancy services regarding the utilization of nuclear technology for socio-economic and environmental development
- Administer and operate the research reactor and other nuclear facilities, and provide nuclear technology and nuclear safety services to the public
- Promote the nuclear network and cooperate with organizations and research institutes, both domestic and international
- Disseminate and build up public acceptance on the utilization of nuclear science and technology for national development

STRATEGY

- Focus on research and development projects which meet the socio-economic and environmental benefits
- Promote cooperation networks with domestic and international organizations
- Develop the efficiency and quality of services of nuclear science and technology, and nuclear safety
- Promote the cooperation network for communication, public relations, and knowledge dissemination to build up understanding and acceptance from all stakeholders and the public
- Make use of advanced and efficient information technology for administration of databases and knowledge, and of technology transfer to the public
- Develop an organizational management system with flexibility for efficient and effective cooperation

One-Stop Service



Thailand Institute of Nuclear Technology (TINT) has now launched the one-stop service center to provide a complete beginning-to-end service solution to facilitate our clients.

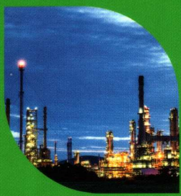
TINT offers a wide range of services on nuclear technology including:

- Radioactivity testing of imported/exported goods
- Qualitative and quantitative elemental analysis
- Radioactivity analysis
- Stable isotope analysis
- Measurement of gross alpha and gross beta particle activities
- Estimates of artifact ages using the carbon-14 technique
- Gamma radiation for research and commercial purposes
- Microorganism analysis
- Tritium measurement in water
- Purchasing, repairing and calibration of survey meters
- Offering research products
- Nuclear technology transfer
- Research and services related to nuclear technology

*Results can be collectedin person at the institute or sent via e-mails or mails.

Nuclear Technology Service Center

Distillation Column Inspection using Gamma Scanning



The gamma scanning technique is one of the most common nuclear techniques on troubleshooting industrial equipmentsuch as distillation columns. This technique utilizes gamma rays which can pass through the column internals. The radiation intensity changes according to the density of the internals. The gamma scanning is used to locate mechanical damage and depict process flow characteristics that cause poor performance in terms of quality and quantity.

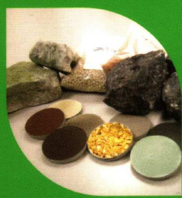
Import/Export Products Radiological Monitoring

TINT offers radioactivity testing service for imported/exported goods. We measure radioactive contamination of exported food and agricultural products as well as issuing any relevant certifications. This is to ensure consumer confidence and supports Thailand's food export industry.

Personnel radiation exposure monitoring

To ensure the safety of people who work in radiation and nuclear facilities, the law stipulates that a person must be exposed to radiation no more than 20 milli-sievert/year in a span of 5 years. TINT offers such tools as thermoluminescent dosimeters (TLD) and opticallystimulated luminescent dosimeters (OSL) to measure human radiation exposure. OSL works similarly as TLD does but uses laser to release the electrons instead of heating. Both tools can detect similar types of ionizing radiation including alpha, beta, gamma, x-rays, and neutrons.

Elemental Analysis



TINT provides elemental analysis using nuclear technology to determine the type and quantity of elemental composition within the samples. We use instruments and techniques including X-Ray Fluorescence (XRF) and Neutron Activation Analysis (NAA). Our institute also employs chemical techniques, such as ICP-AES (Inductively Coupled Plasma - Atomic Emission Spectroscopy).

Radiation Projector for Industry Inspection

Radiography Testing is one of a non-destructive testing method used for material inspection. The radiography testing operates similarly to medical radiography, with the test part or material is placed between the x-ray source and film. Radiation is then directed through the material and onto the film. The resulting shadow on the film shows the internal wholeness of the material. Materials with high density will reduce the penetrating radiation, hence creating white or faint shadows on the film. On the contrary, imperfections contained inside objects, such as holes, will generate black or dark shadows.

Radiographic Testing

To ensure safe and efficient operations, industries needs to regularly examine the structure of their facilities including the materials, objects and equipment of importance. TINT offers non-destructive radiographic testing services to efficiently evaluate the internal structure of the objects of interest without causing any damage.

Calibration laboratory

The Calibration Laboratory offers calibration of various radiation dosimeters including survey meters, pen dosimeters, and electronic personal dosimeters. A radiation dosimeter is an important and useful tool for an individual who is exposed to ionizing radiation as it is used to estimate the radiation dose in the area that the individual is located. Moreover, the dosimeter can also calculate the duration which is safe for the individual to operate in a work site. To maintain the accuracy of the device, it is necessary to undergo routine calibration at least once a year.

Package Inspection

The transportation of radioactive materials must follow regulatory requirements, such as packaging, to ensure safety during shipment. To comply with the national and international safety regulations, before the transportation, the package containing radioactive materials must be inspected to obtain a certificate of approval and labeled to indicate the type and level of hazard.The service center also offers inspection on industrial radiographic equipment in conformity with the radiography safety regulations.

Irradiation and Microorganism Analysis

1 Inhibition of germination
(Doses not exceeding 1 kGy)

Root vegetables, such as onions, shallot, garlic and potatoes, cannot be stored for too long due to their fast germination, which could result in product shortage in the market. To prevent this, gamma irradiation is employed to inhibit their germination. In addition, these vegetables are stored to in a cold room to preserve their freshness. Vegetables which are to be irradiated must be of good-quality and should be stored in transparent containers. They must also be no more than 2 – 4 weeks after harvested. Alternatively, they can be irradiated right after the harvest.

2 Delayed ripening of mushrooms
(Doses not exceeding 2 kGy)

Gamma rays with doses between 1 – 2 kGy can delay the ripening of mushrooms, thereby prolonging the shelf-life.

3 Radiation disinfestation
(Doses not exceeding 2 kGy)

Radiation disinfestation of exported fruits helps enhance Thailand's fruit export industry, especially to the United States of America, which imposes a tough restriction on 7 imported fruits. These fruits are longan, mangosteen, mango, rambutan, pineapple, lychee, and pitaya.

4 Parasite inactivation
(Doses not exceeding 4 kGy)

Irradiation can kill parasites in food, such as roundworms and pork tapeworms.

5 Food preservation
(Doses not exceeding 7 kGy)

Irradiation can preserve food as it prevents the growth of microorganisms that cause spoilage. Ionizing radiation together with cold-room storage can help prolong the shelf-life of various food including meat and seafood.

6 Microorganism and pathogenic microorganism reduction
(Doses between 2 - 20 kGy)

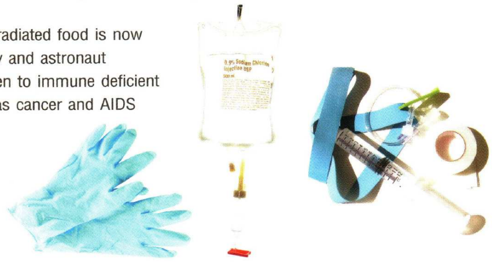
The law on irradiated food issued by Ministry of Public Health requires that irradiated foods shall be exposed to a cumulative maximum absorbed dose of not exceed 10 kGy. Ionizing radiation can reduce the number of microorganisms and pathogenic microorganisms, without compromising sensory attributes or wholesomeness of the food.

7 Sterilization
(Doses between 15 - 50 kGy)

Irradiation can be used for sterilization of injection needles and medical devices that directly contact living tissues. TINT provides the irradiation service for 3 types of healthcare products:

- Medical supplies such as rubber, plastic, cellulose as well as one-time use supplies including surgical devices, thread, nylon, suture needles, syringes, gauze, and plastic lab containers
- Pharmaceutical products such as drugs, solution, saline solution, and other pharmaceutical devices
- Tissues engineered medical products for burn wound healing and transplantation including bones, meninges, and skin

Furthermore, irradiated food is now used as military and astronaut supplies or given to immune deficient patients, such as cancer and AIDS patients.



Microorganism Analysis Laboratory (ISO/IEC 17025:2005) Radiation Centre

Provides analysis of microorganism, pathogenic microorganism, yeasts and fungi in various products including herbs, herb capsules, cordial, bolus, cosmetics, food items, spices, and animal food.

Water Testing Laboratories

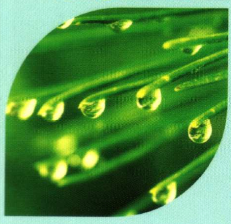
The Radioactive Waste Management Center provides radioactivity testing for wastewater from hospitals, factories and communities.

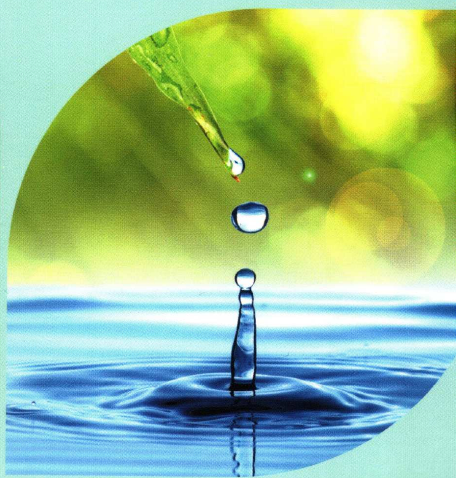
Radioactivity testing for wastewater

The Radioactive Waste Management Center provides alpha and beta particle testing in wastewater. The center also offers the analysis and determination of the concentration of gamma-emitting radionuclides in wastewater samples before dumping. This is to promote human and environmental safety so as to comply with the standard imposed by US Environmental Protection Agency (EPA).

Measurement and Decontamination of wastewater

The measurement and decontamination of wastewater is one of the protocols employed to ensure the radiation safety. The main objective of this is to prevent the radiation spill and the spread of contamination to laboratory personnel, the general public, and the surrounding environment.





Radioactive Waste Management

A leader in safe radioactive waste management for human and the environment

TINT's Radioactive Waste Management Center has a vision of becoming a leader in safe radioactive waste management for human and the environment. Its main mission is to provide the management of radioactive waste for local clients both in government and private sectors. Moreover, the Radioactive Waste Management Center offers the radioactive waste management technology transfer through trainings and operational meetings at national and regional levels. The center is also open to university students and the general public for observation visit.

The Radioactive Waste Management Center treats the safety of the public as its first priority. Certified with ISO9001:2008, the center's practice also conforms to the International Atomic Energy Agency (IAEA) standard.

Radioactive waste management

Radioactive sources from radioactive material applications whose purposes are categorized as follows:

- Research and educational
- Medicine
- Industrial
- Consumer products

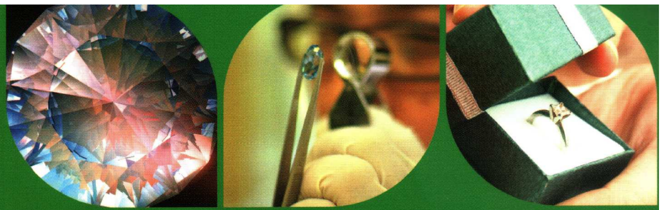
Dismantling of disused radioactive sources

To facilitate and provide end-to-end service for clients who utilize radioactive materials, the Radioactive Waste Management Center offers the dismantling of disused radioactive source service. Clients include factories, research and educational institutes, and medical facilities. Equipped with experienced technicians and facilitating tools, our Waste Management Center is highly specialized in the dismantling of radioactive sources.

Transportation of radioactive wastes

The transportation of radioactive wastes is a part the radioactive waste management. The main objective is to ensure the safety in transporting of the radioactive wastes from clients' premises including hospitals, factories, and research/educational institutes. TINT is specialized in a safe practice of radioactive waste transportation. The institute has drivers who are certified to transport toxic wastes. To comply with the "Measure on transportation of radioactive materials and wastes" issued by Thailand's Office of Atoms for Peace , TINT has also installed a real-time vehicle monitoring system using the Global Positioning System (GPS), radiation protective and detection equipment.

Gems Irradiation Center



The Gems Irradiation Center is a unit under Thailand Institute of Nuclear Technology (TINT). We provide ionizing irradiation service on gemstones for gem dealers as well as clients who want to add market values for their stones by artificially altering their colors. TINT offers a full gem irradiation service as follows:

1. **Gamma Irradiation Service.** TINT provides irradiation for gemstones in a gamma ray facility using the radioactive isotope cobolt-60, which can irradiate up to 2,400 kilograms of gemstones per year. This process artificially enhances the colors of gemstones while adding market values without leaving any residual radioactive isotope.

2. **Electron Irradiation Service.** TINT uses a 20-MeV, 10kW e-beam accelerator for electron bombardment to alter a gemstone's color. This machine is specifically built for gemstone irradiation and capable of irradiating up to 4,800 kilograms of gemstones per year. An electron beam irradiated gemstone has a high specific heat and is prone to cracking. To prevent that, the stone must be cooled down by placing it in water. Treated gemstones can absorb electrons better than gamma ray, and, as a result, the electron treated gemstones produce more vivid colors.

3. **Neutron Irradiation Service.** TINT also offers the gemstone treatment service using a nuclear reactor for neutron bombardment. Neutrons have more penetrating power than electrons. Therefore, when irradiated with neutrons, a gemstone absorbs the neutron beam equally throughout its body. However, exposing gemstones in a nuclear reactor can make them radioactive, the intensity of which is varied in each stone type. The stones need to be set aside to allow residual radioactivity to decay until it reaches a safe level. To comply with the international standard, the residual radioactivity remaining with the stones must not exceed 2 nCi/g.

4. **Measurement of radioactivity in gemstones.** TINT provides the radioactivity measurement for gemstones and issues a letter of certification signed by one of our expert scientist.

The Gems Irradiation Center offers a wide range of irradiation treatment services for precious and semi-precious gemstones, such as Topaz and Tourmarine. A unit under Thailand Institute of Nuclear Technology, the Gems Irradiation Center now becomes a gemstone enhancement center that offers a state-of-the-art, one-stop service center and is the largest in Southeast Asia.

Color enhancement chart for irradiated gemstones

Gemstones	Color Enhancement Summary
Beryl and Aquamarine	From colorless to yellow, blue to green, and light color to dark blue (Maxixe)*
Corundum	From colorless to yellow**, pink to padparadscha**
Diamond	From colorless or faded color to blue, green, black, yellow, brown, pink or red
Pearl	Color enhanced to be more intense gray, brown, blue or black
Quartz	From colorless, yellow, green to smoky, amethyst, and amethyst-citrine
Spodumene or Kunzite	To yellow or green
Topaz	From colorless to yellow**, orange**, brown** or blue
Tourmaline	From colorless or faded color to yellow**, brown**, pink**, red** or bi-color
Zircon	Green-red**, from blue to purple, colorless to brown-red

* Stone color will fade when exposed to light

** Stone color will fade when exposed to light. It is possible that the stones have at least two color centers. One color center will fade, while the other is stable.

Radioisotope Center

TINT's Radioisotope Center is responsible for producing radioisotope, labeled compounds, Tc-99 radiopharmaceutical kits, and sealed source for medical, agricultural, research and educational use.

The radioisotope manufactured by the center are delivered to 25 hospitals and institutes – both in public and private sectors – which help to treat 300,000 patients a year, hence saving at least 23 million baht in drug importation cost for Thailand.

Radioisotope manufacturing via reactor

Nuclear fission process in a research nuclear reactor emits a large quantity of free neutrons in the reactor core. These neutrons can be easily absorbed by many stable elements. Therefore, if these elements are put into the nuclear reactor, they will absorb the neutrons. This process will cause the atomic nuclei to change, thereby producing new radioactive elements.

Such radioisotopes are known as the primary isotopes.

Primary isotopes produced by the Radioisotope Center are summarized as follows:

Radioisotope	Chemical Formula	Benefits
^{131}I	$Na^{131}I$	Used for treatment of Hyperthyroidism; Thyroid cancer and examining of Thyroid uptake.
^{153}Sm	$^{153}SmCl_3$	Used for labeled compounds.
^{32}P	$H_3{}^{32}PO_4$	Used for agricultural research and studies.

Labeled compound

Labeled compound is a compound that is labeled with a primary isotope to yield various benefits as follows:

Type	Benefits
^{131}I-Hippuran	Used for measurement of renal tubular secretion rate.
^{131}I-MIBG	Used for scintigraphy of adrenal glands; treatment of benign pheochromocytoma tumors; treatment of adrenal cancers.
^{153}Sm-EDTMP	Used for pain relief caused by bone metastases.
^{153}Sm-Hydroxyapatite	Used for treatment of rheumatoid.

Products


Thai Silk Shower Gel
250 ml.


Thai Silk Shampoo
250 ml.


Thai Silk Conditioner
200 ml.


Thai Silk Body Lotion
200 ml.


Thai Silk Soap
50 g.


Thai Silk Soap
100 g.


Tint Hand & Nail Butter
50 mg.


Tint Thai Silk Soap
50 g.


ผงไหมซิริซิน


Chitosan
1,000 ml.


Sterilized marl (Tablets)


Sterilized marl (Powder)


Brooch


Ties with tweezers

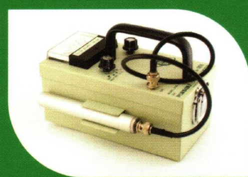

Fruit Insect Trap Solution


Super Water Absorbent
Polymer


Survey Meter Internal Detector
Model 5701-I


Survey Meter Internal Detector
Model 5702-E


Survey Meter Internal Detector
Model 2105-I


Survey Meter Internal Detector
Model 2105-E

Thailand Institute of Nuclear Technology
(Public Organization)
9/9 Moo 7, Sai Moon, Ongkharak, Nakorn Nayok, 26120
Tel. 0 2401 9889 ext 5990 Direct phone 02 579 0743 Fax. 037 392 913
Call Center 02 401 9885


ศูนย์ไอโซโทปรังสี
สถาบันเทคโนโลยีนิวเคลียร์แห่งชาติ (องค์การมหาชน)
กระทรวงวิทยาศาสตร์และเทคโนโลยี
21
อาคารผลิตเภสัชภัณฑ์รังสี
Radiopharmaceutical Production Building
www.tint.or.th

ศูนย์ไอโซโทปรังสี

ศูนย์ไอโซโทปรังสี สถาบันเทคโนโลยีนิวเคลียร์แห่งชาติ (องค์การมหาชน) มีภารกิจหลักคือ ดำเนินการผลิตสารไอโซโทปรังสี (Radioisotopes) สารประกอบติดฉลากรังสี (Labeled Compounds) และสารเภสัช สำเร็จรูป ของเทคนีเชียม-99เอ็ม (Tc-99m Radiopharmaceutical kits) เพื่อใช้ ประโยชน์ในด้านต่างๆ เช่น ทางการแพทย์ ทางการเกษตร การศึกษาวิจัย เป็นต้น

ศูนย์ไอโซโทปรังสีได้ดำเนินการผลิตสารไอโซโทปรังสี เพื่อบริการให้แก่ โรงพยาบาล และสถาบันต่างๆ ทั้งภาครัฐและเอกชนประมาณ 30 แห่ง สามารถบริการผู้ป่วยได้ประมาณ 30,000 คนต่อปี และคาดว่าสามารถ ประหยัดเงินตราของประเทศได้ประมาณปีละไม่น้อยกว่า 2,000 ล้านบาท

การผลิตสารไอโซโทปรังสีจากเครื่องปฏิกรณ์ปรมาณูวิจัย

การผลิตสารไอโซโทปรังสีจากปฏิกิริยานิวเคลียร์ของธาตุเสถียรที่มี ความสามารถในการจับนิวตรอนได้ดีกับนิวตรอนที่เกิดจากปฏิกิริยาการ แบ่งแยกนิวเคลียสของเชื้อเพลิงภายในเครื่องปฏิกรณ์ปรมาณูวิจัย เกิดเป็นธาตุชนิดใหม่ซึ่งมีคุณสมบัติเป็นสารไอโซโทปรังสี

เนื่องจากการผลิตสารไอโซโทปรังสีเป็นการปฏิบัติงานกับรังสีที่มี ความแรงในระดับสูงเพื่อความปลอดภัยของผู้ปฏิบัติงานและสิ่งแวดล้อม โดยรอบ ตู้ปฏิบัติการผลิตไอโซโทปรังสีจึงต้องออกแบบให้สามารถ ป้องกันไม่ให้สารรังสีรั่วไหลหรือแพร่สู่ภายนอก โดยตัวตู้ทำด้วยตะกั่ว หนา และมีกระจกตะกั่วเพื่อให้มองเห็นการทำงาน ซึ่งภายในตู้มีความดัน

บรรยากาศต่ำกว่าภายนอก เพื่อให้อากาศไหลเข้าสู่ภายในตู้ เป็นการป้องกันมิให้สารรังสีรั่วไหลออก พร้อมกันนี้ระบบระบายอากาศจะกักกรองอากาศให้สะอาดก่อนที่จะปล่อยสู่ภายนอก ระบบน้ำทิ้งและของเสียที่มีรังสีจะได้รับการจัดเก็บแยกจากขยะทั่วไป จากนั้นจะส่งไปบำบัดที่ศูนย์จัดการกากกัมมันตรังสี นอกจากนี้บริเวณภายนอกตู้และโดยรอบห้องปฏิบัติการรังสีสูงยังติดตั้งระบบการวัดระดับรังสี เพื่อส่งสัญญาณเตือนให้ทราบ หากมีความผิดพลาดหรือเกิดการรั่วไหลของสารรังสีเกินระดับความปลอดภัยที่กำหนด ตู้ปฏิบัติการผลิตไอโซโทปรังสีทุกชนิดจะประกอบด้วยอุปกรณ์พื้นฐานดังกล่าวข้างต้นเหมือนกัน ส่วนอุปกรณ์อื่นๆ ภายในตู้จะแตกต่างกันตามกระบวนการผลิตสารไอโซโทปรังสีแต่ละชนิด

ขั้นตอนพื้นฐานในการผลิตไอโซโทปรังสีมีดังนี้

01

บรรจุสารตั้งต้นในกระบอกอะลูมิเนียมที่มีความบริสุทธิ์สูงผนึกให้แน่นสนิทแล้วนำไปอาบนิวตรอนในเครื่องปฏิกรณ์ปรมาณูวิจัย

02

ขนย้ายสารตั้งต้นที่อาบนิวตรอนแล้วใส่ภาชนะกำบังรังสีส่งไปยังอาคารผลิตไอโซโทปเพื่อนำสารตั้งต้นเข้าตู้ปฏิบัติการผลิตไอโซโทปรังสี และดำเนินการแยกสารไอโซโทปรังสีที่ต้องการตามกระบวนการที่กำหนดไว้

03 ตรวจสอบคุณภาพ

ทางเคมี ทางชีววิทยา

04

บรรจุหีบห่อและขนส่งไปยังผู้ใช้

ผลิตภัณฑ์ไอโซโทปรังสี ที่ผลิตโดยศูนย์ไอโซโทปรังสี แบ่งเป็น 4 ประเภท คือ

1. สารไอโซโทปปฐมภูมิ (Primary Isotopes) เป็นไอโซโทปของธาตุที่ไม่เสถียร มีการสลายเพื่อลดพลังงานโดยการปล่อยรังสีออกมา ซึ่งผลิตจากเครื่องปฏิกรณ์ปรมาณูวิจัย ได้แก่

สารไอโซโทปรังสี	รูปแบบ	ประโยชน์
^{131}I	$Na^{131}I$	• รักษาโรคไฮเปอร์ไทรอยด์ (Hyperthyroidism) • รักษามะเร็งที่ต่อมไทรอยด์ (Thyroid cancer) • ตรวจสอบการทำงานของต่อมไทรอยด์ (Thyroid Uptake)
^{153}Sm	$^{153}SmCl_3$	• นำมาใช้ในการผลิต 153Sm-EDTMP, 153Sm-HA
^{32}P	$H_3{}^{32}PO_4$	• สำหรับการศึกษา และงานวิจัยทางการเกษตร

2. สารประกอบติดฉลากรังสี (Labeled Compounds) เป็นการนำสารไอโซโทปปฐมภูมิมาติดฉลากกับสารประกอบต่างๆ เพื่อนำมาใช้ในการตรวจวินิจฉัยหรือรักษา ได้แก่

ชนิด	ประโยชน์
^{131}I-Hippuran	• ตรวจสอบอัตราการขับสารทางทูบูลาร์ของไต
^{131}I-MIBG	• ตรวจวินิจฉัย และรักษามะเร็งที่เนื้อเยื่อส่วนกลางของต่อมหมวกไต
^{153}Sm-EDTMP	• บรรเทาอาการปวดจากมะเร็งที่แพร่กระจายไปที่กระดูก
^{153}Sm-Hydroxyapatite	• รักษาโรคเยื่อหุ้มข้ออักเสบ
^{68}Ga-Dotatate	• ตรวจวินิจฉัยเนื้องอกของระบบต่อมไร้ท่อ

Thailand Institute of Nuclear Technology
(Public Organization)

3. สารเภสัชสำเร็จรูปของเทคนีเชียม-99เอ็ม (Radiopharmaceutical Kits) เป็นยาฉีดในรูปผงแห้ง โดยนำมาติดฉลากกับเทคนีเชียม-99เอ็ม เพื่อใช้สำหรับการตรวจวินิจฉัย ได้แก่

ชนิด	ประโยชน์
MDP	• ตรวจวินิจฉัยกระดูก
DTPA	• ถ่ายภาพสมอง • ตรวจอัตราการกรองของไตทางโกลเมอรูลาร์
MAA	• ตรวจวินิจฉัยปอด
DMSA	• ตรวจวินิจฉัยการอักเสบของเนื้อไต
DMSA(V)	• ตรวจวินิจฉัย Medulla Thyroid Cancer
Phytate	• ตรวจวินิจฉัยตับ, ม้ามและปอด
DISIDA	• ตรวจวินิจฉัยทางเดินน้ำดี
Stannous	• ตรวจวินิจฉัยและระบุตำแหน่งเลือดออกในกระเพาะอาหารและลำไส้
MAG_3	• ตรวจวินิจฉัยระบบทางเดินปัสสาวะ
EC	• ตรวจวินิจฉัยระบบทางเดินปัสสาวะ
ECD	• ตรวจวินิจฉัยการไหลเวียนของเลือดในสมอง
Hynic-TOC	• ตรวจวินิจฉัยเนื้องอกของระบบต่อมไร้ท่อ
Ciprofloxacin	• ตรวจวินิจฉัยการอักเสบ

4. สารเภสัชรังสีพร้อมใช้ (Unit doses) เป็นสารเภสัชรังสีที่ติดฉลากกับเทคนีเชียม-99เอ็ม ซึ่งเป็นยาที่เตรียมสำหรับผู้ป่วยเฉพาะราย บรรจุอยู่ในหลอดยาฉีดพร้อมใช้ ได้แก่

ชนิด	ประโยชน์
^{99m}Tc-MDP	• ตรวจวินิจฉัยกระดูก
^{99m}Tc-DTPA	• ถ่ายภาพสมอง • ตรวจอัตราการกรองของไตทางโกลเมอรูลาร์
^{99m}Tc-MAA	• ตรวจวินิจฉัยปอด
^{99m}Tc-DMSA	• ตรวจวินิจฉัยการอักเสบของเนื้อไต
^{99m}Tc-Phytate	• ตรวจวินิจฉัยตับ, ม้ามและปอด
^{99m}Tc-DISIDA	• ตรวจวินิจฉัยทางเดินน้ำดี
^{99m}Tc-MAG_3	• ตรวจวินิจฉัยระบบทางเดินปัสสาวะ
^{99m}Tc-EC	• ตรวจวินิจฉัยระบบทางเดินปัสสาวะ
^{99m}Tc-ECD	• ตรวจวินิจฉัยการไหลเวียนของเลือดในสมอง
^{99m}Tc-Hynic-TOC	• ตรวจวินิจฉัยเนื้องอกของระบบต่อมไร้ท่อ
^{99m}Tc-Ciprofloxacin	• ตรวจวินิจฉัยการอักเสบ

การควบคุมคุณภาพของผลิตภัณฑ์ไอโซโทปรังสี

ผลิตภัณฑ์ไอโซโทปรังสีทุกชนิดที่ผลิตขึ้นจะได้รับการควบคุมคุณภาพจากฝ่ายควบคุมคุณภาพทางด้านต่างๆ ดังนี้

1. ตรวจวัดความบริสุทธิ์ทางนิวไคลด์ (Radionuclidic purity)
2. ตรวจสอบความบริสุทธิ์ทางเคมีรังสี (Radiochemical purity)
3. ตรวจสอบความบริสุทธิ์ทางเคมี (Chemical purity)
4. ตรวจสอบความปลอดเชื้อ (Sterility)
5. Endotoxin test

ศูนย์ไอโซโทปรังสี
สถาบันเทคโนโลยีนิวเคลียร์แห่งชาติ (องค์การมหาชน)
16 ถ. วิภาวดี-รังสิต แขวงลาดยาว เขตจตุจักร กรุงเทพฯ 10900
โทรศัพท์: 0-2579-9560, 0-2401-9889 ต่อ 5400
โทรสาร: 0-2579-9560 | Website: http://www.tint.or.th

AGREEMENT ON ACADEMIC AND EDUCATIONAL EXCHANGE

BETWEEN

Mahidol University
Faculty of Medicine Siriraj Hospital

FACULTY OF MEDICINE SIRIRAJ HOSPITAL
MAHIDOL UNIVERSITY, BANGKOK

....

AND

....

**Agreement on Academic and Educational Exchange Between
Faculty of Medicine Siriraj Hospital, Mahidol University
and ………………………………………………………………..**

with the objective of promoting cooperation in the fields of education, research and academic services, Faculty of Medicine Siriraj Hospital, Mahidol University and ……………………………….. enter into the following Agreement on academic and educational exchange for the mutual benefits.

1. Both parties shall encourage the following activities to expand and promote their mutual interests :
   a) Exchange of students;
   b) Exchange of faculty members and research staff;
   c) Joint research activities;
   d) Support of lectures, research workshops and symposia; and
   e) Exchange of information and academic publications

2. Items pertaining to the implementation of the exchange programs based on this Agreement shall be negotiated and agreed upon between the parties concerned on a case-by-case basis.

3. With regards to the financial obligations of both parties, the visiting party shall cover the transportation and medical expenditures, whereas the host cover the visitor's accommodation and provide assistance and facilitation within a feasible range.

4. This Agreement will be effective for a period of three (3) years upon the date of signing. This Agreement will continue to be in force until either side notifies the other of the intention to terminate in writing. This notification shall be made no later than six (6) months in advance of the termination of the Agreement. Any termination shall not adversely affect any activities already in place or agreed upon.

5. This agreement may be amended by consent of both parties.

In witness of the above, this Agreement is executed in two official copies in English and each party will retain one copy of each.

Professor Dr. Prasit Watanapa
Dean, Faculty of Medicine Siriraj Hospital
Mahidol University

Date :

Date :

Notices under this Agreement shall be addressed to the Parties at the following address :

For ____ :

Authorized Representative	:	
Address	:	
Tel. No.	:	
Fax. No.	:	
Email	:	

For Faculty of Medicine Siriraj Hospital, Mahidol University:

Authorized Representative	:	Dean
Address	:	Faculty of Medicine Siriraj Hospital, Mahidol University 2 Prannok road, Bangkok 10700 Thailand
Tel. No.	:	+ (66-2) 4199465
Fax. No.	:	+ (66-2) 4181621
Email	:	siiro@mahidol.ac.th