行政院原子能委員會核能研究所 委託研究計畫研究報告

核醫造影及影像品保認證與人才交流計畫 Talents exchange and certification of quality assurance in nuclear medicine imaging

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受委託機關(構):行政院國軍退除役官兵輔導委員會臺北榮民總醫院

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中文摘要

因應競爭日益激烈的醫療環境,故本計畫進行臨床核醫造影與影像處理技術訓練教材編制、核醫訓練教具教學手冊編制,透過文件的標準化,檢查流程與儀器品保的範本建立,作為臨床例行檢查的指南與教材,以提升核醫儀器與造影之技術與品質。此外,本計畫與東協國家交流 15 人,在韓國交流 6 人,在印尼交流 3 人,在澳大利亞交流 1 人,在亞太地區國際人才培訓活動中總共交流 25人,並與澳大利亞建立技術交流平台。我們將嘗試在儀器質量保證,成像技術和質量方面促進影像學鑑定,這對我們在該項目中的患者管理而言是正確的事情。收集各國核醫學的臨床應用和發展趨勢的信息,可以作為擴大該國向南政策和提高台灣核醫學國際地位的參考。

Abstract

In response to the increasingly competitive health care environment, purposes of this project intend to establish clinically feasible standard operation procedures in quality control and quality assurance in nuclear instrument, imaging technique and quality and to serve as a comprehensive guide and teaching material in clinical practice of nuclear medicine. The establishment of the SOP will help improve the quality of nuclear medicine clinical technology. In addition, the program exchanged 15 people with ASEAN countries, 6 people in South Korea, 3 people in Indonesia, 1 person in Australia, and a total of 25 people in international talent training activities, and established a technology exchange platform with Australia in the Asia-Pacific region. We will try to promote imaging accreditation in instrument quality assurance, imaging technology and quality that are the right things to do for our patient management in this project. Collecting information on the clinical applications and development trends of nuclear medicine in various countries can be used as a reference for the expansion of the country's southward policy and enhance the international status of nuclear medicine in Taiwan.

壹、計畫緣起與目的

一、計畫緣起

根據國外成功推展核醫藥物上市臨床使用的經驗,藥商或藥物提供單位在藥物上市後,除了需要能夠滿足穩定藥物提供服務之外, 另一項重要關鍵為能夠標準化造影程序與提供配套影像處理工具 以確保常規檢查的影像品質與準確性。

Tc-99m-TRODAT-1 是由核研所開發,2005 年經衛生署核可臨 床使用的造影藥劑;[衛署藥製字第 R000023 號。適應症:對紋狀 體區突觸前神經末稍處之多巴胺轉運體(dopaminergic transporters) 之標示顯影劑,單光子電腦斷層造影(single-photon emission computed tomography; SPECT)的放射製劑]。於 2010 年批准為台灣 中央健保局給付的腦部影像診斷用藥,目前已上市,是核能研究所 第一個成功技轉並外銷到國外的成功案例。Tc-99m-TRODAT-1 先 前的臨床研究結果豐碩,證實可有效檢測多巴胺轉運體不正常所產 生的巴金森病(Parkinson's disease, PD),分辨原發性顫動和多巴胺轉 運體功能萎縮疾病和檢測非典型巴金森氏症(含多發性神經系統退 化症、血管性巴金森氏症、藥物誘發性巴金森氏症、重金屬中毒等 之鑑別)。它對腦部紋狀體多巴胺轉運體有攝取專一性, Tc-99m 獲 取容易,以凍晶型組套問市,易標識;有機會臨床常規化。如能進 一步提升標的特異攝取值,制定影像標準作業流程,將有助臨床確 效性建立,配合藥物銷售、影像品質保證計畫三者結合為完整配套, 以提供全方位服務給使用者;並依此建立院際統一影像判讀與資源 共享將會是未來邁向人工智慧判讀的重要關鍵,其中;在影像品質 提升方面仍有待加強。隨造影儀器的進度,大大提高影像靈敏度及

縮短造影時間,這對 Tc-99m-TRODAT-1 腦部 SPECT 檢查的品質改善是一項利多,有機會改變臨床及核醫醫師的看法,往精準影像醫療方向進行。

本單位目前共有1台專用心臟造影機(GE 530)、二台 SPECT/CT (GE 670、GE 870)、以及五台 SPECT,每天的工作量大約是 120-130 人次,為全國檢查量最多的醫院。對於核醫影像技術之提升,以及人才之培育不惜餘力,所以要有高品質的核醫影像,最重要的因素如下(1)儀器的品管、(2)藥物的品管、(3)影像收集條件最佳化、(4)影像處理分析再現性高、(5)核醫人才培養與訓練。

二、目的

綜上所述,本計畫將進行核醫造影參數最佳化、影像品保認證與人才交流計畫為主。預計收集整理國內外各廠家核醫儀器、核醫影像品保項目、品保之項目與頻次;建立標準作業手冊;於國內一家醫學中心進行品保人員訓練。並且制定 Tc-99m-TRODAT-1、Tc-99m-ECD臨床造影標準流程,進而編制臨床核醫技術訓練教材,並建置提供核醫人員交流與培訓之基地。另外,將積極參與亞太學術交流,擴展國際核醫人脈交流管道,培育亞太區醫療人才來台 20人次,並與一個亞太區國家建立核醫技術交流平台。

貳、研究方法與過程

一、建立核醫技術手冊及設計教育教材

由於各家醫院使用儀器機型、影像截取參數與分析條件、注射藥物後之造影時機、分析及判讀標準等均無統一,因此與核醫學會合作收集整理國內外各廠家儀器、影像品保項目、品保之項目與頻次,建立標準作業手冊,人員進行相關認證訓練,本計畫已經選派三位放射師完成 TAF 財團法人全國認證基金會受訓證明(附件一),藉由種子教師的訓練,設計出有效率的核醫造影技術及值得信賴的病患受檢認證服務,提升病患受檢品質。經由完善規劃的文件整理建檔系統,擬定核醫造影技術認證審查文件。

為了迎接未來人工智慧時代來臨,核醫影像技術以及儀器設備的妥善率為最基本之工程建設。所以我們蒐集美國放射學學會、歐洲核醫學會、國際原子能總署、核醫學教科書文件及參考各家廠商(如西門子、奇異、飛利浦)工作手冊,整理出單光子造影儀(SPECT)必須之品保項目與頻次,並包含各個項目之目的與實踐詳細流程。基於此作為教育教材編制,並培訓臨床品保人員。本院建立之單光子電腦斷層掃描儀(SPECT)臨床品保標準作業手冊如附件二,並於2019/05/30於臺北榮總核醫部進行儀器品保教育宣導(附件三)。設計之公版 SPECT 儀器品保教育訓練課程如附件四。

二、臨床核醫腦神經造影技術訓練講義作業流程

核子醫學在腦部神經系統佔有非常重要的地位,近年來 Tc-99m- TRODAT-1 SPECT 在診斷巴金森氏症有顯著的幫助, Tc-99m-ECD 藥物應用在腦部血流灌注檢查更有不可取代性,但是 檢查技術各家醫院都有不同,為求使核子醫學腦部檢查技術可以更 精進,並促進各醫院更了解該檢查之詳細步驟,尤其在檢查前準備事項,檢查中造影參數設定,以及定量化報告的呈現對於藥物的推廣都很重要。所以在本計畫需求下,完成腦中樞神經疾病造影臨床核醫技術訓練教材編制,教材內容包括 Tc-99m-TRODAT-1 與Tc-99m-ECD 兩項核醫藥物之檢查說明書及造影檢查標準作業流程,並建立公版之臨床核醫腦神經造影技術訓練講義如附件五。

三、人才交流

配合政府南向政策,東南亞國家核子醫學正在萌芽階段,期望透過本計畫培育我國核醫與亞太人才交流,針對核醫醫藥領域與影像技術分析、判讀等課程,建立國內外核醫技術領域人才互訪與培訓平台,透過交流平台將有助於本國核研所生產之核醫藥物成功推銷國外,建立南向行銷通路佈局。

(一)邀請東協核醫人才交流

邀請到來自 4 個東南亞國家(泰國、越南、緬甸及印尼)共 15 位外實,於 2019/07/27 在臺北榮民總醫院核醫部舉辦國際核醫影像品保論壇(International Forum for Quality Assurance in Nuclear Medicine Molecular Imaging),附件六為論壇議程,本次為一天的行程,上午時段主要介紹本院核醫部相關檢查項目尤其在腦部神經、腫瘤和心臟等檢查的技術交流,希望透過此論壇了解各國的核醫現況及檢查步驟。由於病患影像的品質好壞受限於核醫藥物的合成標誌效率,以及掃描儀器有無定期保養檢查其零件效能,故分享台灣目前在單光子電腦斷層儀器的品保項目和品保的頻率和次數。

此外本課程也包含了醫師對於影像判讀技巧之經驗交流,並且 教育核醫影像品質是由影像重組條件所決定,影像訊雜比好,影像 的品質高,才有助於找到微小病兆之變化。並經由各個國家代表都 發言介紹該國核醫現況,詳細結果整理於本文結果與發現。同時實 地帶領外賓參觀核醫部各造影檢查室,介紹新款正子磁振造影儀 (PET/MR),以及迴旋加速器中心之生產正子藥物無塵室觀摩、製藥 室、小動物造影室等(圖一及圖二),並由主持人黃主任介紹台灣核 醫藥物與造影之品保程序(圖三)。下午安排外賓至桃園龍潭核研所 參訪,由張組長介紹核研所核醫製藥中心為通過衛福部 PIC/S GMP 及 GDP 認證之核醫製劑廠,生產氯化亞鉈(鉈-201)注射劑、檸檬酸 鎵(鎵-67)注射劑等放射針劑與馬格鎝腎功能造影劑(MAG3)、美必 鎝心臟造影劑(MIBI)、雙胱乙酯腦血流造影劑(ECD)等凍晶製劑, 提供國內 50 餘家醫院使用,以及核研所相關最新的研究方向。並 參觀其迴旋加速器(圖四)及分子影像設施 PET、SPECT 和 MRI、CT 結合儀器,讓外賓了解透過非侵入式的影像偵檢技術可以清楚地讓 瞭解體內病灶的立體結構,幫助藥物臨床前試驗計劃之成功,會後 東協四國的外賓都表示希望能與我們合作,發展核醫檢查以嘉惠其 病患。

(二)韓國核醫人員技術論壇

2019/11/16 在台南奇美醫院會議中心舉辦國際核醫技術論壇,由本協同計畫主持人楊組長率領核醫技術委員會與6名韓國核醫技術人員進行交流,重點針對在兩國之核醫技術與人才培育之現況討論。首先互相交流雙方核醫正子造影技術之研究成果口頭報告,再針對雙方放射師教育訓練計畫進行交流(圖五)。韓國放射師對於在職繼續教育的制度剛制訂,每4年更新一次,每年要修8個學分(1小時=1學分)。另外在醫院也設有輻射管理委員會,組長需具有輻

防師證照的人才能擔任,增加放射安全之管控能力。韓國在醫事人員的訓練上面是各司其職,韓國醫師和醫事人員都有其獨立的主管 組織系統,互相輔助,各自訓練,互不干預彼此的人員訓練計畫與 本國體制有些微不同。

韓國針對新進人員的訓練方面,有必修的基礎訓練課程必須修滿學分,這部分是看數位教材影片(如衛教感染技術、基礎輻射防護、醫病倫理等等)。此外韓國臨床造影技術則是採用師徒制的教授方式,學長姐一對一跟著教,不像台灣一樣有強制性要求新進人員需受訓兩年計畫(PGY 二年期),也沒有規定期間跟評量方式,由各醫院自行制定新進放射師可以上線臨床服務的時間,韓方覺得本國制度較為完善與嚴謹,是他們未來努力的方向。

相較之下我國放射師缺少專科放射師之認證制度,齊頭平等的 工作環境,因為技術進階向上的制度,將會受限我國核醫技術人員 之發展。相反的在韓國因有專科放射師制度,專科放射師報考資格 須為工作經驗滿五年才能申請資格考試,經由公會考試通過才能拿 到此證照,對於薪水會有加分的部分,使技術人員對於自我的要求 很高,實為病患之福,醫學技術進步之原動力。

(三)開辦 Tc-99m-TRODAT-1 訓練課程

因本國核研所任務在於開發核醫藥物與醫材,發揮進口取代效益,並技轉業界領先創新全球市場發展。如多巴胺轉運體造影劑 (Tc-99m TRODAT-1)為巴金森氏症診斷與療效追蹤利器,2005年核研所取得本國藥品許可證,並已成功達到製藥工業 PIC/S GMP全球化標準,並將其藥證及相關核醫技術與專利技轉於國內廠家製造、生產、銷售等。而本部為國內第一家授證為 T-99m-TRODAT-1

訓練基地,接受國內外核醫單位之申請。因印尼 MRCCC Siloam Hospital 希望發展核醫腦神經診斷技術,尤其在多巴胺轉運體造影 劑(Tc-99m TRODAT-1)之巴金森氏症診斷方面。此醫院是印尼雅 加達最先進的癌症專門醫院,設施完善,各種影像學診斷設備如 PET/CT, MRI、放射線治療儀器等俱全,不遜於任何一家現代化的 醫院。它的擁有者是印尼第二大富豪李文正的家族力寶集團,除了 MRCCC 之外,力寶集團更擁有 18 家連鎖醫院,是印尼最大的醫療 集團。本部於2019/11/25 開辦Tc-99m-TRODAT-1 訓練課程(附件七), 該醫院選派三名醫事人員到本院接受訓練。同行人員有一名核醫醫 師、一名藥師、一名放射師,接受一天的完整受訓計畫。從如何製 備與品管 T-99m-TRODAT-1 藥物, T-99m-TRODAT-1 單光子電腦斷 層掃描檢查前、中、後病患所需的檢查衛教需知。如何利用單光子 電腦斷層掃描儀造影技術參數的設定,影像重建原理介紹,並教導 核醫影像原理及腦神經影像技術定量分析法及影像判讀,受訓人員 均很滿意本次訓練課程,未來期許有合作交流的機會,會繼續保持 聯繫,搭建國際交流之技術平台。

四、與一個亞太區國家建立技術交流平台

因澳洲是核子科技大國,有豐富的天然鈾礦,但因澳洲沒有任何核能發電廠,鈾礦除了出口之外,充份供應當地核子技術及醫藥領域的研究發展非常卓越。前列腺癌是歐美國家男性最常見的癌症。1980年代發現,原發及轉移癌細胞表面有所謂『前列腺特異膜性抗原』(prostate specific membrane antigen; PSMA)表現,此表面抗原便可設計為抗癌細胞的標靶; PSMA 的標靶診斷及治療起源於德國,2015年美國核醫年會最佳年度影像,即是德國團隊以 PSMA-617

標誌 Ga-68 做為診斷造影,標誌 Lu-177 做為治療藥劑而獲得,根 據他們的經驗顯示: 經 Lu-177 PMSA-617 治療後, 血中前列腺特異 膜性抗原(prostate specific antigen; PSA)的量從 38 ng/mL 降至 4.6 ng/mL,顯示其優異的療效,更有研究顯示,低 PSA 不代表低腫瘤 量(PSA does mean low tumor burden), 更彰顯 PSMA 的臨床意義; 澳洲則是在近幾年作很多 Ga-68 PSMA 的造影和治療的研究,雖然 Lu-177 PMSA 治療目前還未通過美國 FDA 核淮上市,大部份的研 究結果都是歐洲醫學中心對於末期轉移性荷爾蒙抗性的前列腺癌 病人(metastatic hormone refractory prostate cancer)的治療經驗,使用 PSMA 做為分子治療工具獲得的顯著療效,也吸引歐美各大藥廠的 關注及投入經費進行前瞻性臨床試驗,希望能夠儘快讓把這個治療 通過查核上市,使用在病人臨床身上。2016 年美國食品暨藥物管 理局(FDA)核准放射藥物 NETSPOT™ (Ga-68 DOTATATE),此藥是 由法國 Advanced Accelerator Applications S.A.公司開發,是第一個 核准上市的 Ga-68 標誌藥物,神經內分泌瘤病人先進行 Ga-68 DOTATATE PET/CT 檢查,以評估病人是否表現腫瘤抗原,Ga-68 DOTATATE 是 octreotide (somatostatin analog)之衍生物,會結合到神 經內分泌腫瘤 (neuroendocrine tumor)表面第二型 somatotatin receptors (SSTRs type 2), 再利用所標誌之 Ga-68 進行 PET 影像診 斷,若有病人的神經內分泌瘤有表現再進行 Lu-177-DOTATATE 治 潦。

本院極力想開發上述兩種核醫診療技術,而澳洲雪梨利物浦醫院(Liverpool Hospital, Sydney Australia)是雪梨西南區最重要的醫院,也是大型的政府公立醫院,臺北榮民總醫院於 2019/11/15 與澳

洲雪梨利物浦醫院簽署合作備忘錄,由張德明院長及澳洲雪梨利物 浦醫院 Peter Lin 教授(Department of Nuclear Medicine and PET at Liverpool Hospital ,Australia)代表雙方簽訂(附件八)。因 PRRT (Peptide Receptor Radionuclide Therapy) 神經內分泌瘤及 PSMA 前列腺癌診療學(Theranostic)為未來核子醫學診斷與治療新藍海,藉由合作備忘錄的簽署,將與澳洲雪梨利物浦醫院展開學術領域相關交流與合作,其中包括共同發展醫學影像與診療技術,開發影像人工智慧工具或研究交流,相信在我們共同的努力下,能為病患提供最好的醫療照護品質。

參、主要發現與結論

一、建立核醫技術手冊及設計教育教材

製作完成腦神經造影劑之臨床核醫技術訓練教材編制,並提供核醫人員交流與培訓。與核醫學會合作收集整理國內外儀器、影像品保項目:完成蒐集美國放射學學會、歐洲核醫學會、國際原子能總署、核醫學教科書文件及參考各家廠商(如西門子、奇異、飛利浦)工作手冊,整理出 SPECT 儀器必須之品保項目與頻率次數,並包含各個項目之目的與實踐詳細流程。本院建立之單光子電腦斷層掃描儀(SPECT)臨床品保標準作業手冊如附件二,並 2019/05/30於臺北榮總核醫部進行儀器品保教育宣導教育(附件三)。SPECT 儀器品保教育訓練課程如附件四。

二、完成臨床核醫腦神經造影技術訓練講義作業流程

整理設計核醫藥物之造影與影像處理技術訓練教材編制,針對醫師、醫事技術人員分別制定核子醫學基礎核心課程、專業進階課程、臨床實習訓練計畫,培育認證種子教官,三位放射師參與TAF認證受訓,預計未來將造影步驟經由第三方機構認證為培訓基地。本次完成編寫腦中樞神經疾病造影臨床核醫技術訓練教材編制,教材內容包括Tc-99m-TRODAT-1與Tc-99m-ECD兩項核醫藥物之檢查說明書及造影檢查標準作業流程。完成之臨床核醫腦神經造影技術訓練講義如附件五。

三、人才交流

本計畫於2019/07/27在臺北榮民總醫院核醫部舉辦國際核醫影像品保論壇(International Forum for Quality Assurance in Nuclear Medicine Molecular Imaging)與東協四國(泰國、越南、緬甸及印尼)

交流 15 人次,東協核醫人才交流國外與會者名單如表一。於 2019/11/16 於台南奇美醫院與韓國核醫人員進行新進核醫人員訓練計畫之技術論壇,與韓國核醫人才交流 6 人次,韓國人才交流名單如表二。於 2019/11/25 於臺北榮總核醫部舉辦之Tc-99m-TRODAT-1 訓練課程,與印尼核醫人才交流 3 人次,印尼人才交流之名單如表三。於 2019/11/15 在臺北榮總致德樓與澳洲雪梨利物浦醫院(Liverpool Hospital, Sydney Australia)簽署合作備忘錄,澳洲為 Peter Lin 醫師 1 人次,本計畫總共完成 25 人次之國際人才交流訓練活動。人才交流之效益遍佈印尼、泰國、緬甸、越南、韓國、澳洲等六國,可以幫助本國核能研究所提供藥物出口以及人才輸出等平台,並且得知以上各國核子醫學之現況,以及蒐集整理出各國核醫現況如下:

(一)東協四國核醫人才交流之各國核醫現況與建議

東協四國醫療市場具有龐大潛力,由各國核醫發展歷史、現況 及未來趨勢可以瞭解,其人員素質及設備將更加專業及新穎,配合 其相對寬鬆法規限制,對於當今核醫分子診療(nuclear molecular theranostics)技術及臨床應用將會更為加速成熟與普遍。收集各國核 醫臨床應用及發展趨勢資訊可作為未來雙方學術、人員交流以及南 向政策拓展之參考,與東協四國核醫人員交流內容如下:

1.泰國

1955 年泰國首度在 Siriraj Hospital 建立核子醫學中心,1977 年 泰國核醫學學會(Nuclear Medicine Society of Thailand, Thai SNM)創 立。至 2019 年,共有 29 間核子醫學中心;包含 22 間政府醫院及 7 間私人醫院。從首間機構創建開始,核子醫學中心的數量都有穩定 的成長;然而擁有 13%人口的曼谷便占了其中的 16 間,可見在快速擴展之餘,區域發展不均、人力短缺也是尚待解決的難題。泰國核醫學學會目前共有 375 位活躍會員,包含 95 位核醫專科醫師、29 位核醫物理師、106 位放射師、32 位藥師、59 位護理師和其他專業人員。

各中心儀器方面,共有 27 台 SPECT gamma camera、16 台 SPECT/CT gamma camera、11 台 PET/CT scanner 及 4 台 迴旋加速器。 年度核醫總造影次數達到 59455 例,最常見的五種掃描分別為: 47.5%骨掃描,12.3%碘-131 全身骨掃描,11.3%心肌掃描,9.3%腫瘤正子掃描及 7.5%甲狀腺掃描。核醫治療方面以甲狀腺相關疾病為主,共佔總體的 99%;其中最常見的為甲狀腺亢進(hyperthyroidism)佔總體比 28.8%,甲狀腺惡性腫瘤 28.8%次之。其餘治療項目 1%為其他疾病,例如: 釔-90 微球體治療(Y-90 microspheres)、骨轉移(bone metastases)、滑膜炎(synovitis)等。

泰國未來重點方向為開發及應用結合診斷治療(theranostic)之放射性核種及加強核醫神經學(nuclear neurology)的推廣。以泰國核醫學會會長 Yuthana Saengsuda 博士完成住院醫師訓練的 King Chulalongkorn Memorial Hospital 為例,2019年首次使用錒-225標誌之 Ac-225-DOTATAT 進行核種標靶的阿伐粒子治療(alpha therapy),因其射程較短,相比傳統貝他射線(beta-emitting)之核種可望能有更高的細胞殺傷效果和較低的副作用,其衰變後之子核種亦可用於治療後造影(posttherapeutic imaging)。核醫神經學目標則以對癲癇、阿茲海默症、帕金森氏症等腦部疾病的功能性變化作深入研究,泰國核醫學會(Thai SNM)已籌辦多次研討會,並與台灣核醫學

會、國際原子能總署(IAEA)、日本核醫學會(Japanese Society of Nuclear Medicine, JSNM)等機構簽訂 MOU, 進行人才訓練和研究交流。

泰國管理放射藥物的架構(framework)由泰國食品藥物管理局 (Thai FDA)的 Achiraya Praisuwan 分享, 泰國由 Office of Atoms for Peace, OAP 負責頒發持有及使用放射性物質的執照,泰國 FDA 負 責管理藥物的臨床前試驗和臨床試驗、上市核可、新藥核可及製造 流程;其職責在於監督放射藥物相關的所有活動,包括臨床、研究 及商業活動,例如:供給、製造、注射、運輸、儲存、分配(distribution)、 進出口等,此外也須確保規範(guideline)能夠在各個單位正確地實 施。放射藥物規章(Regulation)的相關法源為 Drug Act B.E. 2510、 Ministerial Ordinance on Requirements and **Conditions** of Manufacturing of Modern Medicines B.E. 2546 Ministerial Notification on GMP B.E. 2559 及 PIC/S Guide to Good GMP PE 009-12。合法製備、進口放射藥物須獲得 OAP 頒發的執照,並符合 國際醫藥品稽查協約組織(PIC/S)之藥品優良製造規範(GMP)和要 求。

現況上,核醫藥物調製(preparation)須遵循 PIC/S PE010-4,另以 IAEA 和世界衛生組織(WHO)規章作為小規模生產放射藥物及醫院內部(in-house) 生產 PET、治療用放射藥物的補充。放射藥物的品保則根據國際藥典(International Pharmacopeia)發布之期刊論文。未來計畫有二:其一為因應放射藥物的特殊性,發展特定註冊指導方針(guidance)、其二為遵循 PIC/S PE010-4 規章制定符合藥品優良臨床試驗規範(Good Clinical Practice, GCP)的藥物調製指導方針。

2.越南

越南國內目前共有 25 台 SPECT gamma camera、15 台 SPECT/CT gamma camera、12台 PET/CT scanner 及 5台迴旋加速器。核醫相關專業人士包含 163 位核醫專科醫師、45 位核醫物理師、101位放射師、29位藥師、186位護理師。在越南,超過 90%的核醫檢查作為腫瘤科(oncology)之輔助,以醫師 Mai Trong Khoa 博士任職的 Bach Mai Hospital 為例,其配備包含 1台 PET/CT、2台 SPECT、2台 CT simulator 及 1台碘 125 Seed Implant Therapy System、1台迴旋加速器、1台 Gamma knife 及相對應的 MRI simulation、此外還有近接治療(brachytherapy)和釔 90治療的相關設備。PET/CT 影像應用在放射治療,能夠獲得腫瘤的新陳代謝資訊,使得生理標靶體積(biological target volume)能夠被勾畫出來,進而提高放射治療的精確度。

未來方向是可用於混合造影(hybrid imaging)的示蹤劑、以及可結合診斷及治療的核種。另外,目前的藥物供應不足以滿足造影檢查的需求,然而法規如何在開放藥物許可和輻射安全上取得平衡亦是需要多方考量的重點。

Pharmaceutical Business Control Division, Drug Administration of Vietnam (DAV)的副區長 Nguyen Dieu Ha 介紹越南國內的放射藥物管制法規,規章的相關法源為 54/2017/NĐ-CP、155/2018/NĐ-CP、20/TT-BYT,不論是製造、進出口和販賣放射藥物皆須獲得紙本許可文件。交易活動需符合藥事法第 33 條建立相關設備和執業證明(practice certificate)、43-48 條安全性評估與運輸、儲存、分配、買賣之機制、及其他相關原子能法規。製備設施需符合 GMP 標準、備齊相關執照並有單獨之倉儲(warehouse)或區域儲藏放射藥物、擁有符合衛生部(Ministry of Health, MOH)之監視管理系統,且留有相

關檔案記錄。進出口放射藥物除了以上條件外,需配備 GSP/GDP 倉儲(warehouse),且符合相關原子能法規; MOH 才可根據法規54/ND-CP/2017 授予企業進出口執照,此執照有效期為一年。生產、運輸、醫用核可執照由科技部(Ministry of Science and Technology)之輻射安全部門基於原子能法規授予,有效期為一年。

越南的核醫藥物使用皆須獲得藥物註冊序號或進口執照,目前國內有 11 種放射藥物和 1 種進口放射藥物。未來目標為加強放射藥物品保管理,以維護輻射安全及病患安全、加強州政府健康處理廳(State Management Agency on Health)和州政府輻射安全處理廳(State Management Agency on Radiation Safety)資訊交換及人員訓練、爭取 IAEA 與其他國家的合作和協助

3.緬甸

緬甸國內第一個放射性同位素部門於1963年在 Yangon General Hospital 成立,1988年第一個核醫部門由緬甸政府在 Mandalay General Hospital 創立,配備有西門子公司(SIEMENS)製造的 E. CAM single head SPECT Gamma Camera。2003年政府在 Yangon General Hospital 安裝第一台 E. CAM dual head SPECT gamma camera。2016年第一間 PET/CT & Cyclotron Center 成立。至 2019年,共有 4 間醫院提供核醫造影的服務,分別為:Yangon General Hospital, Yangon (YGH)、North Okkalapa General Hospital, Yangon (NOGH)、Mandalay General Hospital, Mandalay (MGH)、Naypyitaw General Hospital, Nay Pyi Taw (NGH)。緬甸核醫學會 Myanmar Society of Nuclear Medicine (MSNM)在 2014成立,理事長為 Kyin Myint 醫師博士,一共有 45 位活躍會員,包含 14 位以上核醫專科

醫師、4位核醫物理師、18位以上放射師、2位藥師和其他專業人員。

然而除了YGH有10位以上醫師和相關技術人員外,另外三家醫院都有人力較為短缺的問題;NOGH和NGH更無常駐的核醫醫學物理師和藥師。此外,身為開發中國家,緬甸的健康保險系統尚未完善,核醫檢查無政府的償付 (reimbursement)也降低醫師和病患使用的意願。在未來發展上,政府的協助將扮演關鍵角色,在有限的預算下,也須積極與世界各國接軌,使核醫技術達到國際認可的水準,以對病患提供適時且完善的服務。

緬甸放射藥物供應公司 Radiance Infinity Co.的執行長,Thet Zay Yar Myint 先生也分享了他們公司相關的業務和目前緬甸的放射藥物法律規範。Radiance Infinity Co., Ltd. 在 2016 年成立,前身為 Lucky Charm Trading Pte Ltd,總部設置在仰光,目前有十位職員,負責供應的上述四間官方醫院及其他私人機構的放射藥物。 Radiance Infinity 與多個國家的生技公司有合作,如美國的 Pharmalucence 和 Biodex、英國的 Lablogic、德國的 ITG-Garching、義大利的 Comecer 等。他們的業務包含放射藥物造影劑供應、放射性實驗室設置(hot-lab setup)、放射治療和影像品保相關儀器、輻射防護相關設備及各種分析用儀器。

緬甸的放射性藥物和儀器規範由 Department of Atomic Energy (DAE)主導,目前 Myanmar FDA 並未參與放射性物質的管理。DAE 的權責包含進出口、運輸、製備及分配等,遵照 IAEA 的法規作為指導方針和參考,細項再根據國家的情況調整。藥物從最初提交申請樣本和必要文件約需半年完成,接著在經過審查程序,到核可共

約需9個月至1年的時間,未來希望加快程序以因應快速發展的市場。

4.印尼

1971 年第一間提供核醫造影服務的醫院為萬隆的 Hasan Sadikin Hospital。1999 年 Hasan Sadikin Hospital/School of Medicine Padjadjaran University 正式培育核醫專科醫師,至今年有近 60 位核醫專科醫師投入臨床服務。國內第一台 SPECT/CT 在 2004 年安裝;第一台 PET/CT 在 2008 年開始服務。由於癌症盛行率(prevalence)的提高,利用同位素進行診斷、治療的核醫需求也不斷地增加。在印尼,主要的核醫治療以碘 131 治療甲狀腺癌位主,其他亦有利用姑息療法 (palliative treatment)治療惡性骨轉移和 ¹³¹I-metaiodobenzylguanidine (MIBG)治療神經胚細胞瘤(neuroblastoma)的應用。

(二) 韓國核醫人員技術論壇

2019/11/16 於台南奇美醫院舉辦與韓國核醫人員技術論壇,共交流6人次。本次交流主要針對核醫正子造影技術口頭報告,以及醫事放射師教育訓練計畫進行交流(圖五)。韓國放射師對於在職繼續教育的制度剛制訂,每4年更新一次,每年要修8個學分(1小時=1學分)。另外在醫院也設有輻射管理委員會,組長需具有輻防師證照的人才能擔任。在韓國醫師和醫事人員都有獨立的主管系統,各自訓練,互不干預彼此的人員訓練。

針對新進人員的訓練方便,有必修的基礎訓練必須上,這部分 是看數位教材影片(衛教感染技術、基礎輻射防護、醫病倫理等等)。 臨床造影技術則是採用師徒制的方式,學長姐一對一跟著教,但不 像台灣一樣有強制性(PGY 二年期),也沒有規定期間跟評量方式,由各醫院自行制定新進放射師可以上線臨床服務的時間。另外韓國有專科放射師制度,報告資格為工作經驗要滿五年才能申請考試,經由公會考試通過才能拿到此證照,對於薪水會有加分的部分。

(三) 開辦 Tc-99m-TRODAT-1 訓練課程

於臺北榮總核醫部開辦 Tc-99m-TRODAT-1 訓練課程表如附件 六;訓練印尼核醫人才 3 人次,參與之核醫單位 MRCCC Siloam Hospital,人員名單:一名醫師、一名藥師、一名放射師,主要訓 練核醫影像原理及腦神經影像技術及影像判讀,以及藥物製備(詳見 附表三及圖六),透過此次訓練,將加速印尼與我們再核醫技術交流 平台之建立。

四、亞太區國家建立技術交流平台

本院於 2019/11/15 與澳洲雪梨利物浦醫院(Liverpool Hospital, Sydney Australia)簽署合作備忘錄(圖七),由張德明院長及澳洲雪梨利物浦醫院 Peter Lin 教授代表雙方簽訂。因 PRRT (Peptide Receptor Radionuclide Therapy 神經內分泌瘤)及 PSMA (Prostate-Specific Membrane Antigen)前列腺癌診療學為未來診療新藍海,藉由合作備忘錄的簽署,本院將與澳洲雪梨利物浦醫院展開學術領域相關交流與合作,其中包括共同發展醫學影像與診療技術,開發影像人工智慧工具或研究交流,相信在我們共同的努力下,能為病患提供最好的醫療照護品質。透過本計畫培育我國核醫與亞太人才交流,針對核醫醫藥領域與影像技術分析、判讀等課程,建立國內外核醫技術領域人才互訪與培訓平台,透過交流平台將有助於本國核研所生產之核醫藥物輸出成功推銷國外,建立南向行銷通路

佈局。

五、結論

為了迎接未來人工智慧時代來臨,核醫影像技術以及儀器設備的妥善率為最基本之基礎建設,本計畫完成蒐集美國放射學學會、歐洲核醫學會、國際原子能總署、核醫學教科書文件及參考各家廠商(如西門子、奇異、飛利浦)工作手冊,整理出 SPECT 儀器必須之品保項目與頻率次數,並包含各個項目之目的與實踐詳細流程。可基於此作為教育教材編制,並培訓臨床品保人員,並於臺北榮總核醫部進行儀器品保教育宣導教育。

另外,本計畫完成腦中樞神經疾病造影臨床核醫技術訓練教材編制,教材內容包括 Tc-99m-TRODAT-1 與 Tc-99m-ECD 兩項核醫藥物之檢查說明書及造影檢查標準作業流程。

在人才交流方面,與東協四國交流 15 人次,韓國交流 6 人次, 印尼交流 3 人次,澳洲 1 人次,共交流達 25 人次。與一個亞太區 國家(澳洲雪梨利物浦醫院)建立技術交流平台,共同發展醫學影像 與診療技術,開發影像人工智慧工具或研究交流。透過本計畫培育 我國核醫與亞太人才交流,針對核醫醫藥領域與影像技術分析、判 讀等課程,建立國內外核醫技術領域人才互訪與培訓平台,透過交 流平台將有助於本國核研所生產之核醫藥物輸出成功推銷國外,建 立南向行銷通路佈局。

綜所上述,本計畫完成人才培育基地軟硬體建置,與核醫學會合作,有助於國內未來推動核醫品保認證計畫;與亞太國家建立核醫技術交流平台,雙方互訪與訓練其人才外,透過連結東協核醫人才,延伸國產核醫藥物出口東協國家機會。東協國家醫療市場具有

龐大潛力,由各國核醫發展歷史、現況及未來趨勢可以瞭解,其人 員素質及設備將更加專業及新穎,配合其相對寬鬆法規限制,對於 當今核醫分子診療(nuclear molecular theranostics)技術及臨床應用 將會更為加速成熟與普遍。收集該各國核醫臨床應用及發展趨勢資 訊可作為未來雙方學術、人員交流以及南向政策拓展之參考。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。

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附件一、TAF 財團法人全國認證基金會受訓證明



財團法人全國認證基金會 Taiwan Accreditation Foundation

參加證書

證書號碼:TAF-MM108004-P-27

茲證明<u>楊邦宏</u>君於中華民國 108 年 4 月 23 日 至 108 年 4 月 25 日假台北參加「醫學實驗室認證規範 ISO 15189 訓練」共計 18 小時。

許景行

許景行/財團法人全國認證基金會執行長

中華民國一〇八年四月二十五日



財團法人全國認證基金會 Taiwan Accreditation Foundation

參加證書

證書號碼:TAF-MM108004-P-25

茲證明<u>張嘉容</u>君於中華民國 108 年 4 月 23 日 至 108 年 4 月 25 日假台北參加「醫學實驗室認證規範 ISO 15189 訓練」共計 18 小時。

許景行

許景行/財團法人全國認證基金會執行長

中華民國一〇八年四月二十五日



財團法人全國認證基金會 Taiwan Accreditation Foundation

參加證書

證書號碼: TAF-MM108004-P-26

茲證明<u>陳苓仕</u>君於中華民國 108 年 4 月 23 日 至 108 年 4 月 25 日假台北參加「醫學實驗室認證規範 ISO 15189 訓練」共計 18 小時。

許景行

許景行/財團法人全國認證基金會執行長

中華民國一〇八年四月二十五日

附件二、SPECT 儀器品保手册

單光子電腦斷層掃描儀(SPECT) 臨床品保標準作業手冊

臺 北 榮 總 核 醫 部

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驗收測試 (Acceptance Test)

Time to perform

Immediately after installation, and before clinical use

Purpose

- 1. Ensure that the performance of an instrument meets the technical specifications quoted by the manufacturer
- 2. Record as reference baseline for the routine QA testing

Tests

Tests
Physical inspection
Intrinsic flood field uniformity
Intrinsic spatial resolution
System planar sensitivity
Intrinsic count rate performance
Multiple window spatial registration
Detector head shielding leakage
Physical inspection
Intrinsic flood field uniformity
Intrinsic spatial resolution
System planar sensitivity
Intrinsic count rate performance
Multiple window spatial registration
Detector head shielding leakage

Physical inspection

Purpose

- Ensure no potential shipping damage and production design flaws

- Ensure all instruments are well-functioning by inspecting:
 - 1. Detector housing and support assembly
 - 2. Control panels
 - 3. Image display devices
 - 4. Image recording devices
 - 5. Hand control
 - 6. Emergency devices
 - 7. Mobile cameras
 - 8. Collimators
 - 9. Electrical connections
 - 10. Fuses and cables
 - 11. Data storage and display devices
- Operation and service manuals should also be available

Intrinsic flood field uniformity

Purpose

Ensure uniform response of imaging systems to spatially uniform photon flux

Implementation

- Remove the collimator from the detector head, mount the point source container which consisting of 10–20 MBq (0.3–0.5 mCi)
 99mTc solution and position a lead mask (Figure 2Figure 1Figure 1.)
- Acquire an image with approximately 3,000k counts, use a matrix size that produces pixel sizes with a linear dimension of $6.4 \text{ mm} \pm 30\%$
- Visually inspect the image for variations in brightness or density
- Use NEMA method for image data processing, set pixels in the central field of view (CFOV) with less than 75% mean counts to zero after resizing and perform a nine point smoothing
- Determine the maximum (max) and minimum (min) counts in pixels within the useful field of view (UFOV) and the CFOV
- The integral uniformity and differential uniformity are given by:
- integral uniformity = $100 * \left[\frac{(\text{max-min})}{(\text{max+min})} \right]$
- differential uniformity = $100 * \left[\frac{\text{(high-low)}}{\text{(high+low)}} \right]$

Where high and low are the pixel counts giving the highest value of the maximum count difference

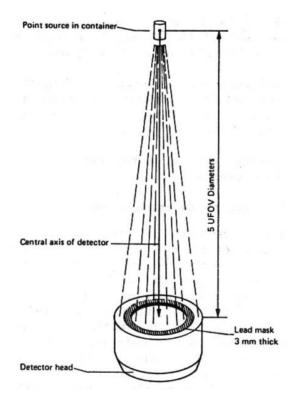


Figure 1. Mounting of the point source. (Image acquired from IAEA Human Health Series no. 6)

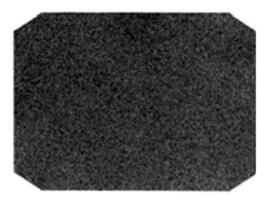


Figure 2. Routine intrinsic uniformity image, ^{99m}Tc, 3 million counts, 20% energy window set symmetrically over the 140 keV photopeak. The image shows good uniformity. (Image acquired from IAEA Human Health Series no. 6)

Intrinsic spatial resolution

Purpose

 Ensure the ability of scintillation camera to accurately determine the position of incoming photons

- A bar phantom is placed directly on the uncollimated detector and irradiated by the point source placed away at a distance ($\geq 5X$ UFOV)
- Acquire an image at a preset count of 60k, use the largest matrix size available
- The intrinsic spatial resolution can be approximated as FWHM = 1.75⋅B, where B is the width of the narrowest bars that the scintillation camera can still resolve

System planar sensitivity

Purpose

 Test the count rate response of a scintillation camera to a radionuclide source of known radioactivity

- Set a planar sensitivity phantom containing an accurately known amount of radioactivity, mount collimator on the detector head and cover it with a plastic sheet, then place the phantom 10 cm from the collimator surface
- Collect an image for over 100 s, record the total counts and exact time of day; remove the phantom, then count and record the background for the same time
- Repeat the above steps for all other low energy collimators; and repeat above steps with phantom containing ⁶⁷Ga or ¹¹¹In for medium energy collimators and ¹³¹I for high energy collimators
- Correct the data for the decay time and background, calculate the planar sensitivity of each collimator in counts per second per becquerel or equivalent units to match the manufacturer's specifications

Intrinsic count rate performance

Purpose

Test the response of scintillation camera to an increasing photon flux

- Use a point source consisting of about 4 MBq (100-500 mCi) of 99m
 To solution in a suitable container
- Remove the collimator from the detector head, mount the source on the movable stand and ensure the source is on the central axis of the detector
- Register the count rate as the source is moved towards to the detector face, record the maximum count rate
- The value of the maximum count rate should be compared with the manufacturer's worst case value

Multiple window spatial registration

Purpose

 Ensure that the images acquired at different photon energies superimpose when more than one PHA is used simultaneously

- Remove the collimator and turn the head to face horizontally, a ⁶⁷Ga point source is placed on a table adjacent to the scintillation camera
- The default PHA windows is set on the 93, 184 and 296 keV photopeaks and adjust the source activity not to exceed a count rate of 10,000 counts/s
- Acquire separate images through each of the PHA channels with 5,000K counts using the largest FOV available, and acquire an image with all three PHA channels contributing
- Position the source on the X+/X-/Y+/Y- axes of the detector face at about 75% of the distance from the center to the edge, remove the source and measure the distance between the two X and two Y source positions; also determine the coordinates of the X and Y source positions on each image, using count profiles or ROIs
- The locations at which the sources appear with the highest counts should coincide

Detector head shielding leakage

Purpose

 Ensure that the detector head responds only to radiation incident upon the crystal after transmission through the collimator

- Use point sources consisting of 4 MBq (100 mCi) 99mTc and a radionuclide having an energy that corresponds to the maximum design energy of the camera
- Mount the collimator, position the source at twelve sites (as shown in figure.1) around the detector head shielding, and record the number of counts at each site for 100 s
- Position the source in the center of the field of view at a distance of 10 cm from the face of the collimator for 100 s, then remove the source and measure the background count for 100 s
- Calculate the shielding leakage (%) by dividing this maximum count by the count obtained through the collimator
- For 99m Tc, leakage should be negligible; for higher energy radionuclides, leakage should meet the manufacturer's specification

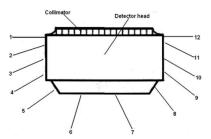


Figure 3. The twelve point source position. (Image acquired from IAEA Human Health Series no. 6)

Absolute pixel size

Purpose

To determine the absolute pixel size in the matrix

- Place the point source on the camera face along the X axis, about 5 cm from the edge of FOV
- Set up the system to perform a static acquisition of 50K counts using the finest possible matrix size and acquire one planar image
- Move the point source horizontally to a position about 5 cm away from the other edge of the FOV, by a distance known to within 1 mm; repeat the acquisition
- Repeat the whole procedure by placing the point sources along the Y axis
- Repeat for all tomographic zoom conditions used in clinical practice
- Calculate the center of gravity (COG) of the point source(s) for each image and obtain the distances between the position of each COG pairs:

-
$$COGx = \frac{\sum_{i=i_1}^{i_2} \sum_{j=j_1}^{j_2} i \times MATRIX(i,j)}{\sum_{i=i_1}^{i_2} \sum_{j=j_1}^{j_2} MATRIX(i,j)}$$

- along a profile of thickness j₁ to j₂ and width i₁ to i₂ bounding the
 point source, where i is the index of the matrix along the X axis and j
 corresponds to Y axis
- distance $X = \sqrt{(X_1 X_2)^2 + (Y_1 Y_2)^2}$
- The difference between the values in X and Y should be less than 5%

Center of rotation offset and alignment

Purpose

Test the center of rotation (COR) offset, alignment of the camera Y axis and head tilt with respect to the axis of rotation

- Suspend the ^{99m}Tc point source in air within about 2 cm of the axis
 of rotation and within about 2 cm of the center of the field of view
- Perform a acquisition using the finest matrix size available, collecting about 10K counts at every angular position (32 angles over 360° is considered adequate)
- Repeat the above steps but place the point source as far as possible away from the central slice
- The offset from the center of rotation (R) could be calculate as:
- $R = (N + 1 X_0 X_{180})/2$
- X_0 is the COGX at 0° and X_{180} is the COGX at 180° degrees, N is the number of pixels across the image (e.g. N=256 if the data were collected in 256 x 256)

Tomographic uniformity of the camera

Purpose

 Test the tomographic uniformity of a rotating scintillation camera SPECT system

Implementation

- Ensure that all the camera uniformity correction calibration procedures have been correctly performed
- Place the tomographic uniformity phantom with its center at least within 2 cm of the axis of rotation, as close as possible to the center of rotation
- Set up a tomographic acquisition using a normal matrix size and clinical protocol, collecting a total of about 1M counts per slice, then perform uniformity correction as recommended by the manufacturer and reconstruct the data with a ramp filter
- Identify the minimum or maximum value corresponding to the location of a ring artefact as seen in the reconstructed image. Record this value as Cmin/max
- Record the two values along the profile of the uniform source just beyond the edges of the artefact identified in step (3), terming them C1 and C2, then the contrast could be estimated:

$$- C_{ave} = \frac{(C1+C2)}{2}$$

$$- contrast = \frac{c_{min/max} - c_{ane}}{c_{min/max} + c_{ane}}$$

 The planar uniformity of a scintillation camera when used in SPECT should be better than 4%

Tomographic resolution in air

Purpose

 Ensure the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction

- Place the point source in air within 1 cm of the center of rotation, set the radius of rotation to be approximately 15 cm, perform a acquisition using the matrix size and number of angles used clinically; collecting about 10K counts per view
- Reconstruct the data with filtered backprojection and ramp filter
- Perform a normal planar (static) acquisition at the home position, using the same acquisition condition as for the tomographic acquisition
- Repeat above steps with the point source placed about 8 cm off axis, and the point source placed on the axis of rotation, but close to the edge of the field of view
- Draw a profile through the image of the point source in the reconstructed image and calculate the FWHM in both the horizontal and the vertical directions

Tomographic resolution with scatter

Purpose

 Check the tomographic resolution of the system in clinical conditions

- Use resolution phantom with central hole filled with high specific activity ^{99m}Tc, place the center of the phantom within 2 cm of the center of rotation and close to the center of FOV
- Adjust the radius and collect data as the method described in the test of tomographic resolution in air
- Move the phantom so that its center is about 5 cm away from the axis of rotation and repeat above steps with a larger radius of rotation
- Draw profiles through the reconstructed image of the point source;
 both horizontally and vertically, then measure the FWHM, on the horizontal and vertical profiles

Slice thickness at center of slice

Purpose

 Teat the slice thickness to ensure that the spatial resolution along the tomographic Z axis is within limits

- The data is collected as the same method as for the test of tomographic resolution in air
- Locate the slice in which the point source is most clearly seen and locate the pixel in which the maximum number of counts is observed;
 Note the (X, Y) coordinates of this pixel and its maximum value
- Record the number of counts at this same (X, Y) pixel position for all slices adjacent to and including the slice in which the maximum was found, such that all slices containing counts of more than 5% of the maximum are included
- Generate a profile of the point source along the Z axis using these values, calculate the FWHM of this profile

Variations of sensitivity and uniformity

with rotation of the system

Purpose

 Determine the variations in system sensitivity as a function of angular position of the detector

- Attach the flood source firmly to the camera, perform a tomographic acquisition with at least about 1M counts per angle
- For a system collecting data by continuous rotation, record the total rotation time, and repeat the test for both fast and slow rotation
- Repeat for any other heads
- Find the total number of counts collected at each angle, correct for decay time and calculate the mean, standard deviation and maximum deviation
- calculate the NEMA integral uniformity for each angular position

Overall system performance

Purpose

Verify that the system is performing adequately in a high count study

- Use a total performance phantom, the activity contained should be about 400 MBq (10 mCi) of ^{99m}Tc
- Set up the phantom and acquire a tomographic study using the acquisition time in order to collect 800K counts for each projection, 120 projections, a matrix size of 128 × 128 and a 360° angle of rotation
- Reconstruct the data with filtered backprojection and a ramp filter
- The images should be carefully inspected for artifacts, the linear attenuation coefficient and contrast should be calculated

常規測試 (Routine Test)

Time to perform

Daily, weekly, monthly, quarterly to semi-annually, and annually

Purpose

Ensure the optimum performance of an instrument at all times and to determine and extent of any deterioration in that performance with time

Tests

lests	
Daily	Visual and physical inspection
	Uniformity
	Energy peaking and window
	Cine and sinogram data review
	Background count rate
Weekly	Intrinsic or extrinsic (system) spatial resolution and linearity
	High-count flood and uniformity
Monthly	Center of rotation
Quarterly - semi-annually	Overall system performance
	System flood field uniformity
	System planar sensitivity
	Intrinsic count rate performance
	Reconstructed point source resolution
	Tilt-angle check
	Absolute pixel size
	Tomographic uniformity of the camera
	Tomographic resolution in air
	Tomographic resolution with scatter
	Slice thickness at center of slice
Annually	Collimator hole angulation
	Multiple window spatial registration

Visual and physical inspection

Purpose

- Ensure imaging quality and patient or staff safety

Implementation

 Visual and physical inspection of detector heads and collimators, touch pad, and emergency stop buttons, if available

Uniformity

Purpose

Ensure uniform response of imaging systems to spatially uniform photon flux

Implementation

(As per described in the acceptance test section.)

Intrinsic uniformity

- Remove the collimator from the detector head; extra care must be taken to ensure that exposed crystals are not damaged
- A refillable or a solid ⁵⁷Co flood source is used to track source activity and count rate for each uniformity acquisition, usually a 3,000K counts for a small rectangular FOV and a 5,000K counts for a large rectangular FOV would be considered appropriate
- Use NEMA method for image data processing, set pixels in the central field of view (CFOV) with less than 75% mean counts to zero after resizing and perform a nine point smoothing
- Determine the maximum (max) and minimum (min) counts in pixels within the useful field of view (UFOV) and the CFOV
- The integral uniformity and differential uniformity are given by:
- integral uniformity = $100 * \left[\frac{(\text{max-min})}{(\text{max+min})} \right]$
- differential uniformity = $100 * \left[\frac{\text{(high-low)}}{\text{(high+low)}}\right]$
- Where high and low are the pixel counts giving the highest value of the maximum count difference

Extrinsic (system) uniformity

- The process is similar to the intrinsic uniformity test, but with the collimator mounted on the detector head
- Collimator defects may appear as linear artefacts covering large or small areas of the image

Energy peaking and window

Purpose

- Ensure correct energy calibration of the system

Implementation

Operational checks of energy window settings to confirm that all
pulse height analyzer energy windows are properly centered around
the energy photopeaks of the radionuclides to be used for clinical
imaging purposes

Cine and sinogram data review

Purpose

 Rule out axial shift and transverse COR errors of multi-detector systems

• Implementation

 Visually inspect any truncation, patient motion, and possible count variations between frames

Background count rate

Purpose

Detect possible radioactive contamination

- Operational check of the background count rates with or without collimators, and within various energy windows
- Background count rates should be approximately constant in all directions to rule out contamination of the scintillation camera, floor or walls, neighboring source or an excess of electronic noise

Intrinsic or extrinsic (system) spatial

resolution and linearity

Purpose

 Ensure the ability of scintillation camera to accurately determine the position of incoming photons

Implementation

Intrinsic spatial resolution

(As per described in the acceptance test section.)

- A bar phantom is placed directly on the uncollimated detector and irradiated by the point source placed away at a distance (≥ 5X UFOV)
- The intrinsic spatial resolution is approximated as FWHM = 1.75 ⋅B, where B is the width of the narrowest bars that the scintillation camera can still resolve

Extrinsic spatial resolution and spatial linearity

- The bar phantom is placed directly on the collimated detector and irradiated by the point source placed away at a distance (≥ 5X length of the detector)
- After collecting the required number of counts, the spatial resolution is expressed as the narrowest stripes resolvable on the acquired images

High-count flood and uniformity

Purpose

 verify uniformity within the field of view of the scintillation camera and proper uniformity/sensitivity correction

- The total number of counts is collected and a pixel-by-pixel multiplication of a raw image by the ratio image is calculated, this corrects the non-uniformities in the detector and the collimator
- The data may be acquired using the same setup as used for the daily uniformity test, except that a much larger number of counts (tens to one or a few hundred million) must be acquired

Center of rotation (COR)

Purpose

Ensure the image reconstruction process is consistently aligned with the mechanical COR

- Check the alignments in both the x- and the y-axis, using point sources of similar activities of 99mTc placed in the same plane in the air, on and off the axis of rotation and the center of the field of view
- Point sources are imaged at an even number of detector angular positions equally distributed over 360°, each detector must be positioned parallel and must acquire an image at 0° and 180°
- COR error should stay within acceptable limits given in millimeters
- Recommended weekly to monthly testing frequency, depending on the stability of the SPECT system

Overall system performance

Purpose

- Check overall SPECT system performance

- cylindrical tomographic phantoms (e.g. Jaszczak phantom, Carlson phantom) are filled with ^{99m}Tc and high-count data is acquired and reconstructed with filtered backprojection and a ramp filter
- Reconstructed images are used to detect possible ring artifacts and distorted spheres and rods, to evaluate the contrast and spatial resolution of objects of a known size and to calculate the linear attenuation coefficient for attenuation correction

System flood field uniformity

Purpose

 Test the system flood field response of a scintillation camera for all collimators used

- Mount the collimator on the detector head and turn the head to face vertically upward, place the flood phantom at a distance of about 10 cm above the face
- Acquire an image of 30K counts and a matrix size of 512×512 , then remove the flood phantom
- Repeat above steps for all collimators used
- Visually inspect the images for any variations in brightness or density not apparent in the corresponding intrinsic flood field image
- Collimator defects may appear as linear artefacts covering large or small areas of the image

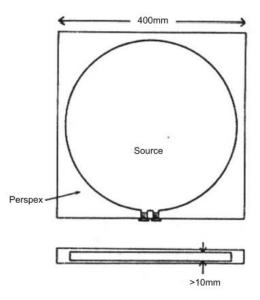


Figure 4. Flood phantom, fabricated in plastic (e.g. Lucite, Perspex), which provides a uniform flood source when filled with ^{99m}Tc in solution. The diameter of the liquid filled area should be 5 cm greater than the UFOV. (Image acquired from IAEA Human Health Series no. 6)

System planar sensitivity

Purpose

 Test the count rate response of a scintillation camera to a radionuclide source of known radioactivity

Implementation

- Set a planar sensitivity phantom containing an accurately known amount of radioactivity, mount collimator on the detector head and cover it with a plastic sheet, then place the phantom 10 cm from the collimator surface
- Collect an image for over 100 s, record the total counts and exact time of day; remove the phantom, then count and record the background for the same time
- Repeat the above steps for all other low energy collimators; and repeat above steps with phantom containing ⁶⁷Ga or ¹¹¹In for medium energy collimators and ¹³¹I for high energy collimators
- Correct the data for the decay time and background, calculate the planar sensitivity of each collimator in counts per second per becquerel or equivalent units to match the manufacturer's specifications

Intrinsic count rate performance

Purpose

Test the response of scintillation camera to an increasing photon flux

- Use a point source consisting of about 4 MBq (100-500 mCi) of 99m
 To solution in a suitable container
- Remove the collimator from the detector head, mount the source on the movable stand and ensure the source is on the central axis of the detector
- Register the count rate as the source is moved towards to the detector face, record the maximum count rate
- The value of the maximum count rate should be compared with the manufacturer's worst case value

Reconstructed point source resolution

Purpose

- Examine errors in COR and detector positioning

- Check the width in all three dimensions, shape, and presence of streaking or other artifacts in the reconstructed image
- This test could be carried out at the same time as a COR test with the same point source

Tilt-angle check

Purpose

Ensure the position of projection data is consistently aligned

- The angle of tilt is the angle between the detector plane and the axis of rotation, measured along the axis of rotation, it should remain 0° for all angles of rotation
- The angle of tilt can be determined from summed projection images over 360° of a radioactive point source placed off the axis of rotation

Absolute pixel size

Purpose

To determine the absolute pixel size in the matrix

Implementation

- Place the point source on the camera face along the X axis, about 5 cm from the edge of FOV
- Set up the system to perform a static acquisition of 50K counts using the finest possible matrix size and acquire one planar image
- Move the point source horizontally to a position about 5 cm away from the other edge of the FOV, by a distance known to within 1 mm; repeat the acquisition
- Repeat the whole procedure by placing the point sources along the Y axis
- Repeat for all tomographic zoom conditions used in clinical practice
- Calculate the center of gravity (COG) of the point source(s) for each image and obtain the distances between the position of each COG pairs:
- $COGx = \frac{\sum_{i=i_1}^{i_2} \sum_{j=j_1}^{j_2} i \times MATRIX(i,j)}{\sum_{i=i_1}^{i_2} \sum_{j=j_1}^{j_2} MATRIX(i,j)}$
- along a profile of thickness j₁ to j₂ and width i₁ to i₂ bounding the
 point source, where i is the index of the matrix along the X axis and j
 corresponds to Y axis
- distance $X = \sqrt{(X_1 X_2)^2 + (Y_1 Y_2)^2}$
- The difference between the values in X and Y should be less than
 5%

Tomographic uniformity of the camera

Purpose

 Test the tomographic uniformity of a rotating scintillation camera SPECT system

Implementation

(As per described in the acceptance test section.)

- Ensure that all the camera uniformity correction calibration procedures have been correctly performed
- Place the tomographic uniformity phantom with its center at least within 2 cm of the axis of rotation, as close as possible to the center of rotation
- Set up a tomographic acquisition using a normal matrix size and clinical protocol, collecting a total of about 1M counts per slice, then perform uniformity correction as recommended by the manufacturer and reconstruct the data with a ramp filter
- Identify the minimum or maximum value corresponding to the location of a ring artefact as seen in the reconstructed image. Record this value as Cmin/max
- Record the two values along the profile of the uniform source just beyond the edges of the artefact identified in step (3), terming them C1 and C2, then the contrast could be estimated:

$$- C_{ave} = \frac{(C1+C2)}{2}$$

$$- contrast = \frac{c_{min/max} - c_{ane}}{c_{min/max} + c_{ane}}$$

 The planar uniformity of a scintillation camera when used in SPECT should be better than 4%

Tomographic resolution in air

Purpose

 Ensure the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction

Implementation

- Place the point source in air within 1 cm of the center of rotation, set the radius of rotation to be approximately 15 cm, perform a acquisition using the matrix size and number of angles used clinically; collecting about 10K counts per view
- Reconstruct the data with filtered backprojection and ramp filter
- Perform a normal planar (static) acquisition at the home position, using the same acquisition condition as for the tomographic acquisition
- Repeat above steps with the point source placed about 8 cm off axis, and the point source placed on the axis of rotation, but close to the edge of the field of view
- Draw a profile through the image of the point source in the reconstructed image and calculate the FWHM in both the horizontal and the vertical directions

Tomographic resolution with scatter

Purpose

 Check the tomographic resolution of the system in clinical conditions

Implementation

- Use resolution phantom with central hole filled with high specific activity ^{99m}Tc, place the center of the phantom within 2 cm of the center of rotation and close to the center of FOV
- Adjust the radius and collect data as the method described in the test of tomographic resolution in air
- Move the phantom so that its center is about 5 cm away from the axis of rotation and repeat above steps with a larger radius of rotation
- Draw profiles through the reconstructed image of the point source;
 both horizontally and vertically, then measure the FWHM, on the
 horizontal and vertical profiles

Slice thickness at center of slice

Purpose

 Teat the slice thickness to ensure that the spatial resolution along the tomographic Z axis is within limits

Implementation

- The data is collected as the same method as for the test of tomographic resolution in air
- Locate the slice in which the point source is most clearly seen and locate the pixel in which the maximum number of counts is observed;
 Note the (X, Y) coordinates of this pixel and its maximum value
- Record the number of counts at this same (X, Y) pixel position for all slices adjacent to and including the slice in which the maximum was found, such that all slices containing counts of more than 5% of the maximum are included
- Generate a profile of the point source along the Z axis using these values, calculate the FWHM of this profile

Collimator hole angulation

Purpose

 Check the septal alignment and angulation for all parallel hole collimators used

- A point source is placed a few meters from the collimator, in the center of each parallel hole collimator and in four or more other positions approximately halfway to the edge of the field of view
- Acquired images should be visually inspected and checked for any asymmetries, streaks and distortions
- New collimator should be provided by the manufacturer if the collimator holes and septa do not aligned appropriately

Multiple window spatial registration

Purpose

 Ensure that the images acquired at different photon energies superimpose when more than one PHA is used simultaneously

Implementation

(As per described in the acceptance test section.)

- Remove the collimator and turn the head to face horizontally, a ⁶⁷Ga point source is placed on a table adjacent to the scintillation camera
- The default PHA windows is set on the 93, 184 and 296 keV photopeaks and adjust the source activity not to exceed a count rate of 10,000 counts/s
- Acquire separate images through each of the PHA channels with 5,000K counts using the largest FOV available, and acquire an image with all three PHA channels contributing
- Position the source on the X+/X-/Y+/Y- axes of the detector face at about 75% of the distance from the center to the edge, remove the source and measure the distance between the two X and two Y source positions; also determine the coordinates of the X and Y source positions on each image, using count profiles or ROIs
- The locations at which the sources appear with the highest counts should coincide

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附件三、SPECT 儀器品保訓練討論會

臺北榮民總醫院 核醫部 各項討論會會議紀錄

中華民國 108年 05 月 30 日(星期 四)

類別 ()臨床病歷討論會 ()外科組織病理討論會 ()雜誌码	开討會						
討論會 ()影像診療研討會 ()教學查房 ()其他:							
主題 SPECT 儀器品保項目討論會							
主持人 職稱:部主任 報告人 職稱:醫事放射師							
姓名:黃文盛 姓名:楊邦宏							
時間 15 時 40 分至 17 時 00 分 地點 核醫部會議室							
福度在京海道等表表等的							
1. 報告國內外各廠家核醫儀器、核醫影像品保項目、品保之項目與頻	次。						
2. 討論單光子儀器品保標準作業程序。							
3. 下表為 SPECT 儀器建議品保項目以及頻次。							
項目	頻率						
Visual and physical inspection	毎日						
Uniformity	毎日						
Energy peaking and window	毎日						
Cine and sinogram data review	毎日						
容 Background Count Tate	毎日						
摘 Intrinsic or extrinsic (system) spatial resolution	毎週						
要 and linearity	与 网						
討 High-count flood and uniformity	每週						
Center of rotation	每月						
例 0verall system performance	每季~每半年						
出 System flood field uniformity	每季~每半年						
High-count flood and uniformity	每季~每半年						
回 Reconstructed point source resolution	每季~每半年						
Tilt-angle check	每季~每半年						
Absolute pixel size	每季~每半年						
Tomographic uniformity of the camera	每季~每半年						
Tomographic resolution in air	每季~每半年						
Tomographic resolution with scatter	每季~每半年						
Slice thickness at center of slice	每季~每半年						
Collimator hole angulation	毎年						
Multiple window spatial registration	毎年						

建議整理成標準作業手冊,提供放射師與儀器廠商參考之依據						
論						
紀錄	大人 主持人簽名: 核醫部 黄文盛					

註:1. 討論名稱請以(√)勾選。2. 本紀錄請自行影印,一份留部(科)存查,一份定期送教學組,於每月三日前結算。3. 不敷使用請另紙繼續。

附件四、SPECT 儀器品保教育訓練課程投影片

Quality Assurance (QA) for Single Photon Emission Computed Tomography (SPECT)

Outline

- Preamble
- Overall list of tests
- Acceptance test
- Routine test:
 - Daily
 - Monthly
 - Quarterly to semi-annually
 - Annually
- References

Preamble

- This presentation is aim to serve as a guideline for the hospitals in Taiwan, the purpose and Implementation of each test is listed in the following sections
- The QA schedule for SPECT system after installation and routine performance is collected from (in alphabetical order):
 - American College of Radiology (ACR)
 - European Association of Nuclear Medicine (EANM)
 - International Atomic Energy Agency (IAEA)
 - International Electrotechnical Commission (IEC)
 - National Electrical Manufacturers Association (NEMA)
- Manufacturers of the SPECT system include GE, Philips, Toshiba, and Siemens

Overall list of tests

Test	Frequency
Physical inspection	After installation
Intrinsic flood field uniformity	After installation
Intrinsic spatial resolution	After installation
System planar sensitivity	After installation
Intrinsic count rate performance	After installation
Multiple window spatial registration	After installation
Detector head shielding leakage	After installation
Physical inspection	After installation
Intrinsic flood field uniformity	After installation
Intrinsic spatial resolution	After installation
System planar sensitivity	After installation
Intrinsic count rate performance	After installation
Multiple window spatial registration	After installation
Detector head shielding leakage	After installation
Visual and physical inspection	Daily
Uniformity	Daily
Energy peaking and window	Daily
Cine and sinogram data review	Daily
Background count rate	Daily

Overall list of tests (cont.)

Test	Frequency
Intrinsic or extrinsic (system) spatial resolution	Weekly
and linearity	
High-count flood and uniformity	Weekly
Center of rotation	Monthly
Overall system performance	Quarterly to semi-annually
System flood field uniformity	Quarterly to semi-annually
System planar sensitivity	Quarterly to semi-annually
Intrinsic count rate performance	Quarterly to semi-annually
Reconstructed point source resolution	Quarterly to semi-annually
Tilt-angle check	Quarterly to semi-annually
Absolute pixel size	Quarterly to semi-annually
Tomographic uniformity of the camera	Quarterly to semi-annually
Tomographic resolution in air	Quarterly to semi-annually
Tomographic resolution with scatter	Quarterly to semi-annually
Slice thickness at center of slice	Quarterly to semi-annually
Collimator hole angulation	Annually
Multiple window spatial registration	Annually

Acceptance test

• Time to perform

Immediately after installation, and before clinical use

Purpose

- Ensure that the performance of an instrument meets the technical specifications quoted by the manufacturer
- Record as reference baseline for the routine QA testing

Acceptance test

Acceptance test

- Physical inspection
- Intrinsic flood field uniformity
- Intrinsic spatial resolution
- System planar sensitivity
- Intrinsic count rate performance
- Multiple window spatial registration
- Detector head shielding leakage

Acceptance test

- Absolute pixel size
- · Center of rotation offset and alignment
- Tomographic uniformity of the camera
- Tomographic resolution in air
- Tomographic resolution with scatter
- Slice thickness at center of slice
- Variations of sensitivity and uniformity with rotation of the system
- Overall system performance

Physical inspection

- Purpose
 - Ensure no potential shipping damage and production design flaws
- Implementation
 - Ensure all instruments are well-functioning by inspecting detector housing and support assembly, control panels, image display devices, image recording devices, hand control, emergency devices, mobile cameras, collimators, electrical connections, fuses and cables, and data storage and display devices
 - Operation and service manuals should also be available

Intrinsic flood field uniformity

Purpose

- Ensure uniform response of imaging systems to spatially uniform photon flux

Implementation

- Remove the collimator from the detector head, mount the point source container which consisting of 10–20 MBq (0.3–0.5 mCi) ^{99m}Tc solution and positioning a lead mask
- $-\,$ Acquire an image with approximately 3,000k counts, ue a matrix size that produces pixel sizes with a linear dimension of 6.4 mm \pm 30%
- Visually inspect the image for variations in brightness or density
- Use NEMA method for image data processing, set pixels in the central field of view (CFOV) with less than 75% mean counts to zero after resizing and perform a nine point smoothing
- Determine the maximum (max) and minimum (min) counts in pixels within the useful field of view (UFOV) and the CFOV
- The integral uniformity and differential uniformity are given by:
- integral uniformity = $100 * \left[\frac{(max-min)}{(max+min)}\right]$
- differential uniformity = $100 * \left[\frac{\text{(high-low)}}{\text{(high+low)}} \right]$
- Where high and low are the pixel counts giving the highest value of the maximum count difference

Intrinsic spatial resolution

Purpose

 Ensure the ability of scintillation camera to accurately determine the position of incoming photons

- A bar phantom is placed directly on the uncollimated detector and irradiated by the point source placed away at a distance (≥ 5X UFOV)
- Acquire an image at a preset count of 60k, use the largest matrix size available
- The intrinsic spatial resolution can be approximated as FWHM = 1.75·B, where B is the width of the narrowest bars that the scintillation camera can still resolve

System planar sensitivity

Purpose

 Test the count rate response of a scintillation camera to a radionuclide source of known radioactivity

Implementation

- Set a planar sensitivity phantom containing an accurately known amount of radioactivity, mount collimator on the detector head and cover it with a plastic sheet, then place the phantom 10 cm from the collimator surface
- Collect an image for over 100 s, record the total counts and exact time of day; remove the phantom, then count and record the background for the same time
- $-\,$ Repeat the above steps for all other low energy collimators; and repeat above steps with phantom containing $^{67}{\rm Ga}$ or $^{111}{\rm In}$ for medium energy collimators and $^{131}{\rm I}$ for high energy collimators
- Correct the data for the decay time and background, calculate the planar sensitivity of each collimator in counts per second per becquerel or equivalent units to match the manufacturer's specifications

Intrinsic count rate performance

Purpose

Test the response of scintillation camera to an increasing photon flux

- Use a point source consisting of about 4 MBq (100-500 mCi) of 99m Tc solution in a suitable container
- Remove the collimator from the detector head, mount the source on the movable stand and ensure the source is on the central axis of the detector
- Register the count rate as the source is moved towards to the detector face, record the maximum count rate
- The value of the maximum count rate should be compared with the manufacturer's worst case value

Multiple window spatial registration

Purpose

 Ensure that the images acquired at different photon energies superimpose when more than one PHA is used simultaneously

Implementation

- Remove the collimator and turn the head to face horizontally, a ⁶⁷Ga point source is placed on a table adjacent to the scintillation camera
- The default PHA windows is set on the 93, 184 and 296 keV photopeaks and adjust the source activity not to exceed a count rate of 10,000 counts/s
- Acquire separate images through each of the PHA channels with 5,000K counts using the largest FOV available, and acquire an image with all three PHA channels contributing
- Position the source on the X+/X-/Y+/Y- axes of the detector face at about 75% of the distance from the center to the edge, remove the source and measure the distance between the two X and two Y source positions; also determine the coordinates of the X and Y source positions on each image, using count profiles or ROIs
- The locations at which the sources appear with the highest counts should coincide

Detector head shielding leakage

Purpose

 Ensure that the detector head responds only to radiation incident upon the crystal after transmission through the collimator

Implementation

- Use point sources consisting of 4 MBq (100 mCi) 99mTc and a radionuclide having an energy that corresponds to the maximum design energy of the camera
- Mount the collimator, position the source at twelve sites (as shown in figure) around the detector head shielding, and record the number of counts at each site for 100 s
- Position the source in the center of the field of view at a distance of 10 cm from the face of the collimator for 100 s, then remove the source and measure the background count for 100 s
- Calculate the shielding leakage (%) by dividing this maximum count by the count obtained through the collimator
- For 99m Tc, leakage should be negligible; for higher energy radionuclides, leakage should meet the manufacturer's specification

Image from IAEA Human Health Series no. 6

Absolute pixel size

Purpose

- To determine the absolute pixel size in the matrix

Implementation

- Place the point source on the camera face along the X axis, about 5 cm from the edge of FOV
- Set up the system to perform a static acquisition of 50K counts using the finest possible matrix size and acquire one planar image
- Move the point source horizontally to a position about 5 cm away from the other edge of the FOV, by a distance known to within 1 mm; repeat the acquisition
- Repeat the whole procedure by placing the point sources along the Y axis
- Repeat for all tomographic zoom conditions used in clinical practice
- Calculate the center of gravity (COG) of the point source(s) for each image and obtain the distances between the position of each COG pairs:

$$- \quad \text{COGx} = \frac{\sum_{i=i_1}^{i_2} \sum_{j=j_1}^{j_2} \text{i} \times \text{MATRIX(i,j)}}{\sum_{i=i_1}^{i_2} \sum_{j=j_1}^{j_2} \text{MATRIX(i,j)}}$$

- along a profile of thickness j₁ to j₂ and width i₁ to i₂ bounding the point source, where i is the index of the matrix along the X axis and j corresponds to Y axis
- distance $X = \sqrt{(X_1 X_2)^2 + (Y_1 Y_2)^2}$
- The difference between the values in X and Y should be less than 5%

Center of rotation offset and alignment

Purpose

Test the center of rotation (COR) offset, alignment of the camera Y axis and head tilt with respect to the axis of rotation

- $-\,$ Suspend the $^{99\rm m}{\rm Tc}$ point source in air within about 2 cm of the axis of rotation and within about 2 cm of the center of the field of view
- Perform a acquisition using the finest matrix size available, collecting about 10K counts at every angular position (32 angles over 360° is considered adequate)
- Repeat the above steps but place the point source as far as possible away from the central slice
- The offset from the center of rotation (R) could be calculate as:
- $R = (N + 1 X_0 X_{180})/2$
- X₀ is the COGX at 0° and X₁₈₀ is the COGX at 180° degrees, N is the number of pixels across the image (e.g. N=256 if the data were collected in 256 x 256)

Tomographic uniformity of the camera

Purpose

Test the tomographic uniformity of a rotating scintillation camera SPECT system

Implementation

- Ensure that all the camera uniformity correction calibration procedures have been correctly performed
- Place the tomographic uniformity phantom with its center at least within 2 cm of the axis of rotation, as close as possible to the center of rotation
- Set up a tomographic acquisition using a normal matrix size and clinical protocol, collecting a total of about 1M counts per slice, then perform uniformity correction as recommended by the manufacturer and reconstruct the data with a ramp filter
- Identify the minimum or maximum value corresponding to the location of a ring artefact as seen in the reconstructed image. Record this value as Cmin/max
- Record the two values along the profile of the uniform source just beyond the edges of the artefact identified in step (3), terming them C1 and C2, then the contrast could be estimated:

$$- \quad C_{ave} = \frac{(C1+C2)}{2}$$

$$- contrast = \frac{c_{min/max} - c_{ane}}{c_{min/max} + c_{ane}}$$

 $-\$ The planar uniformity of a scintillation camera when used in SPECT should be better than 4%

Tomographic resolution in air

Purpose

 Ensure the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction

- Place the point source in air within 1 cm of the center of rotation, set the radius of rotation to be approximately 15 cm, perform a acquisition using the matrix size and number of angles used clinically; collecting about 10K counts per view
- Reconstruct the data with filtered backprojection and ramp filter
- Perform a normal planar (static) acquisition at the home position, using the same acquisition condition as for the tomographic acquisition
- Repeat above steps with the point source placed about 8 cm off axis, and the
 point source placed on the axis of rotation, but close to the edge of the field
 of view
- Draw a profile through the image of the point source in the reconstructed image and calculate the FWHM in both the horizontal and the vertical directions

Tomographic resolution with scatter

Purpose

Check the tomographic resolution of the system in clinical conditions

Implementation

- Use resolution phantom with central hole filled with high specific activity ^{99m}Tc, place the center of the phantom within 2 cm of the center of rotation and close to the center of FOV
- Adjust the radius and collect data as the method described in the test of tomographic resolution in air
- Move the phantom so that its center is about 5 cm away from the axis of rotation and repeat above steps with a larger radius of rotation
- Draw profiles through the reconstructed image of the point source; both horizontally and vertically, then measure the FWHM, on the horizontal and vertical profiles

Slice thickness at center of slice

Purpose

 Teat the slice thickness to ensure that the spatial resolution along the tomographic Z axis is within limits

- The data is collected as the same method as for the test of tomographic resolution in air
- Locate the slice in which the point source is most clearly seen and locate the pixel in which the maximum number of counts is observed; Note the (X, Y) coordinates of this pixel and its maximum value
- Record the number of counts at this same (X, Y) pixel position for all slices adjacent to and including the slice in which the maximum was found, such that all slices containing counts of more than 5% of the maximum are included
- Generate a profile of the point source along the Z axis using these values, calculate the FWHM of this profile

Variations of sensitivity and uniformity with rotation of the system

Purpose

 Determine the variations in system sensitivity as a function of angular position of the detector

Implementation

- Attach the flood source firmly to the camera, perform a tomographic acquisition with at least about 1M counts per angle
- For a system collecting data by continuous rotation, record the total rotation time, and repeat the test for both fast and slow rotation
- Repeat for any other heads
- Find the total number of counts collected at each angle, correct for decay time and calculate the mean, standard deviation and maximum deviation
- calculate the NEMA integral uniformity for each angular position

Overall system performance

Purpose

Verify that the system is performing adequately in a high count study

- Use a total performance phantom, the activity contained should be about 400 MBg (10 mCi) of ^{99m}Tc
- Set up the phantom and acquire a tomographic study using the acquisition time in order to collect 800K counts for each projection, 120 projections, a matrix size of 128 \times 128 and a 360° angle of rotation
- Reconstruct the data with filtered backprojection and a ramp filter
- The images should be carefully inspected for artifacts, the linear attenuation coefficient and contrast should be calculated

Routine Test: Daily

Daily

- Visual and physical inspection
- Uniformity
- Energy peaking and window
- Cine and sinogram data review
- Background count rate

Visual and physical inspection

- Purpose
 - Ensure imaging quality and patient or staff safety
- Implementation
 - Visual and physical inspection of detector heads and collimators, touch pad, and emergency stop buttons, if available

Uniformity

- Purpose
 - Ensure uniform response of imaging systems to spatially uniform photon flux
- Implementation

Intrinsic uniformity

- Remove the collimator from the detector head; extra care must be taken to ensure that exposed crystals are not damaged
- A refillable or a solid ⁵⁷Co flood source is used to track source activity and count rate for each uniformity
 acquisition, usually a 3,000K counts for a small rectangular FOV and a 5,000K counts for a large rectangular
 FOV would be considered appropriate
- Use NEMA method for image data processing, set pixels in the central field of view (CFOV) with less than 75% mean counts to zero after resizing and perform a nine point smoothing
- Determine the maximum (max) and minimum (min) counts in pixels within the useful field of view (UFOV) and the CFOV
- The integral uniformity and differential uniformity are given by:
- integral uniformity = $100 * \left[\frac{(\text{max-min})}{(\text{max+min})} \right]$
- differential uniformity = $100 * \left[\frac{\text{(high-low)}}{\text{(high+low)}} \right]$
- Where high and low are the pixel counts giving the highest value of the maximum count difference

Extrinsic (system) uniformity

- The process is similar to the intrinsic uniformity test, but with the collimator mounted on the detector head
- Collimator defects may appear as linear artefacts covering large or small areas of the image

Uniformity (cont.)

• Manufacturer's intrinsic uniformity quotes:

GE Infinia Qua		ilts: anufacturer's Quote	Toshiba 7200		ntitative Results:		Ma	s/CardioEpic Quantitativ	e Results:
Integral	UFOV	3.60%	Integral	UFOV	6.5%	Integral	UFOV	2.50%	
Uniformity	CFOV	3.00%	Uniformity	CFOV	3.3%	Uniformity	CFOV	2.50%	
Differential	UFOV	2.30%	-	Name of the last o		Differential	UFOV	2.00%	
			Differential	UFOV	4.5%	Uniformity	CFOV	1.50%	
Uniformity	CFOV	2.10%	Uniformity	CFOV	2.8%				
						Philips Skylight (Quantitative	Results:	
			Toshiba T.Cam Quantitative Results:			Manufacturer's Quote			
GE MG Quantit				Ma	nufacturer's Quote	Integral	UFOV	2.50%	
		anufacturer's Quote	Integral	UFOV	3.70%	Uniformity	CFOV	2.00%	
Integral	UFOV	3.50%	Uniformity	CFOV	2.90%				
Uniformity	CFOV	3.00%				Differential	UFOV	2.00%	
•			Differential	UFOV	2.70%	Uniformity	CFOV	1.50%	
Differential	UFOV	2.50%	Uniformity	CFOV	2.50%	DEIII CII- MI	D 0	P	
Uniformity	CFOV	2.00%				Philips Cardio M		nufacturer's Quote	
						QC check results	ma	2.5%	
GE VG Quantit	ative Results:	:				QO OHCON TOSUILS		2.070	
Manufacturer's Quote					Siemens C.Cam Quantitative Results:				
Integral	UFOV	4.80%				Oldinons O.Oum		nufacturer's Quote	
Uniformity	CFOV	3.60%				QC check results	***************************************	2.5%	
Differential	UFOV	3.20%				Siemens E.Cam	Quantitative	Results:	
Uniformity	CFOV	3.00%					Ma	nufacturer's Quote	
o.m.o.m.ny	0. 0.	0.0070				Integral	UFOV	3.70%	
						Uniformity	CFOV	2.90%	
						Differential	UFOV	2.70%	
						Uniformity	CFOV	2.50%	
Data from	n ACR Nuclea	r Medicine Techn	ologist Quality	Control List					

Cine and sinogram data review

Purpose

 Rule out axial shift and transverse COR errors of multi-detector systems

• Implementation

 Visually inspect any truncation, patient motion, and possible count variations between frames

Energy peaking and window

Purpose

- Ensure correct energy calibration of the system

Implementation

 Operational checks of energy window settings to confirm that all pulse height analyzer energy windows are properly centered around the energy photopeaks of the radionuclides to be used for clinical imaging purposes

Background count rate

- Purpose
 - Detect possible radioactive contamination
- Implementation
 - Operational check of the background count rates with or without collimators, and within various energy windows
 - Background count rates should be approximately constant in all directions to rule out contamination of the scintillation camera, floor or walls, neighboring source or an excess of electronic noise

Routine Test: Weekly

Weekly

- Intrinsic or extrinsic (system) spatial resolution and linearity
- High-count flood and uniformity

Intrinsic or extrinsic (system) spatial resolution and linearity

Purpose

 Ensure the ability of scintillation camera to accurately determine the position of incoming photons

Implementation

Intrinsic spatial resolution

- A bar phantom is placed directly on the uncollimated detector and irradiated by the point source placed away at a distance (≥ 5X UFOV)
- The intrinsic spatial resolution is approximated as FWHM = 1.75·B, where B is the width of the narrowest bars that the scintillation camera can still resolve

Extrinsic spatial resolution and spatial linearity

- The bar phantom is placed directly on the collimated detector and irradiated by the point source placed away at a distance (≥ 5X length of the detector)
- After collecting the required number of counts, the spatial resolution is expressed as the narrowest stripes resolvable on the acquired images

Images should be reviewed qualitatively.

Worst $\geq 3.5 \text{ mm}$ $\geq 4.0 \text{ mm}$ Data from ACR Nuclear Medicine Technologist Quality Control List

High-count flood and uniformity

Purpose

 verify uniformity within the field of view of the scintillation camera and proper uniformity/sensitivity correction

- The total number of counts is collected and a pixel-by-pixel multiplication of a raw image by the ratio image is calculated, this corrects the non-uniformities in the detector and the collimator
- The data may be acquired using the same setup as used for the daily uniformity test, except that a much larger number of counts (tens to one or a few hundred million) must be acquired

Routine Test: Monthly

Monthly

Center of rotation (COR)

Center of rotation

- Purpose
 - Ensure the image reconstruction process is consistently aligned with the mechanical COR
- Implementation
 - Check the alignments in both the x- and the y-axis, using point sources of similar activities of ^{99m}Tc placed in the same plane in the air, on and off the axis of rotation and the center of the field of view
 - Point sources are imaged at an even number of detector angular positions equally distributed over 360°, each detector must be positioned parallel and must acquire an image at 0° and 180°
 - COR error should stay within acceptable limits given in millimeters
 - Recommended weekly to monthly testing frequency, depending on the stability of the SPECT system

Routine Test: Quarterly to semi-annually

Quarterly to semi-annually

- Overall system performance (with phantom)
- System flood field uniformity
- System planar sensitivity
- Intrinsic count rate performance
- · Reconstructed point source resolution
- Tilt-angle check
- · Absolute pixel size
- · Tomographic uniformity of the camera
- · Tomographic resolution in air
- · Tomographic resolution with scatter
- Slice thickness at center of slice

Overall system performance

- Purpose
 - Check overall SPECT system performance
- Implementation
 - cylindrical tomographic phantoms (e.g. Jaszczak phantom, Carlson phantom) are filled with ^{99m}Tc and high-count data is acquired and reconstructed with filtered backprojection and a ramp filter
 - Reconstructed images are used to detect possible ring artifacts and distorted spheres and rods, to evaluate the contrast and spatial resolution of objects of a known size and to calculate the linear attenuation coefficient for attenuation correction

Spatial R	esolution	Contrast	
	Rods visible		Spheres visi
Best	9.5 high contrast	Best	12.7 high contrast
	11.1 high contrast		15.9 high contrast
	11.1 low contrast		19.1 high contrast
	12.7 and larger		12.7 low contrast
Worst	<u>> 15.9</u>	Worst	<u>></u> 31.8

Uniformity

Images should be reviewed qualitatively. Data from ACR Nuclear Medicine Technologist Quality Control List

System flood field uniformity

Purpose

 Test the system flood field response of a scintillation camera for all collimators used

Implementation

- Mount the collimator on the detector head and turn the head to face vertically upward, place the flood phantom at a distance of about 10 cm above the face
- Acquire an image of 30K counts and a matrix size of 512 \times 512, then remove the flood phantom
- Repeat above steps for all collimators used
- Visually inspect the images for any variations in brightness or density not apparent in the corresponding intrinsic flood field image
- Collimator defects may appear as linear artefacts covering large or small areas of the image

System planar sensitivity

Purpose

 Test the count rate response of a scintillation camera to a radionuclide source of known radioactivity

- Set a planar sensitivity phantom containing an accurately known amount of radioactivity, mount collimator on the detector head and cover it with a plastic sheet, then place the phantom 10 cm from the collimator surface
- Collect an image for over 100 s , record the total counts and exact time of day; remove the phantom, then count and record the background for the same time
- Repeat the above steps for all other low energy collimators; and repeat above steps with phantom containing 67 Ga or 111 In for medium energy collimators and 131 I for high energy collimators
- Correct the data for the decay time and background, calculate the planar sensitivity of each collimator in counts per second per becquerel or equivalent units to match the manufacturer's specifications

Intrinsic count rate performance

Purpose

Test the response of scintillation camera to an increasing photon flux

Implementation

- Use a point source consisting of about 4 MBq (100-500 mCi) of 99m Tc solution in a suitable container
- Remove the collimator from the detector head, mount the source on the movable stand and ensure the source is on the central axis of the detector
- Register the count rate as the source is moved towards to the detector face, record the maximum count rate
- The value of the maximum count rate should be compared with the manufacturer's worst case value

Reconstructed point source resolution

Purpose

- Examine errors in COR and detector positioning

- Check the width in all three dimensions, shape, and presence of streaking or other artifacts in the reconstructed image
- This test could be carried out at the same time as a COR test with the same point source

Tilt-angle check

Purpose

Ensure the position of projection data is consistently aligned

Implementation

- The angle of tilt is the angle between the detector plane and the axis of rotation, measured along the axis of rotation, it should remain 0° for all angles of rotation
- The angle of tilt can be determined from summed projection images over 360° of a radioactive point source placed off the axis of rotation

Absolute pixel size

- Purpose
 - To determine the absolute pixel size in the matrix
- Implementation
 - Place the point source on the camera face along the X axis, about 5 cm from the edge of FOV
 - Set up the system to perform a static acquisition of 50K counts using the finest possible matrix size and acquire one planar image
 - Move the point source horizontally to a position about 5 cm away from the other edge of the FOV, by a distance known to within 1 mm; repeat the acquisition
 - Repeat the whole procedure by placing the point sources along the Y axis
 - Repeat for all tomographic zoom conditions used in clinical practice
 - Calculate the center of gravity (COG) of the point source(s) for each image and obtain the distances between the position of each COG pairs:

$$- \quad \text{COGx} = \frac{\Sigma_{i=i_{1}}^{i_{2}} \sum_{j=j_{1}}^{j_{2}} \sum_{i > MATRIX(i,j)}^{i_{2}}}{\Sigma_{i=i_{1}}^{i_{2}} \sum_{j=j_{1}}^{j_{2}} \max(i,j)}$$

- along a profile of thickness j₁ to j₂ and width i₁ to i₂ bounding the point source, where i is the index of the matrix along the X axis and j corresponds to Y axis
- distance $X = \sqrt{(X_1 X_2)^2 + (Y_1 Y_2)^2}$
- $-\ \ \,$ The difference between the values in X and Y should be less than 5%

Tomographic uniformity of the camera

Purpose

Test the tomographic uniformity of a rotating scintillation camera SPECT system

Implementation

- Ensure that all the camera uniformity correction calibration procedures have been correctly performed
- Place the tomographic uniformity phantom with its center at least within 2 cm of the axis of rotation, as close as possible to the center of rotation
- Set up a tomographic acquisition using a normal matrix size and clinical protocol, collecting a total of about 1M counts per slice, then perform uniformity correction as recommended by the manufacturer and reconstruct the data with a ramp filter
- Identify the minimum or maximum value corresponding to the location of a ring artefact as seen in the reconstructed image. Record this value as Cmin/max
- Record the two values along the profile of the uniform source just beyond the edges of the artefact identified in step (3), terming them C1 and C2, then the contrast could be estimated:

$$- \quad C_{ave} = \frac{(C1+C2)}{2}$$

 $- contrast = \frac{c_{min/max} - c_{ane}}{c_{min/max} + c_{ane}}$

- The planar uniformity of a scintillation camera when used in SPECT should be better than 4%

Tomographic resolution in air

Purpose

 Ensure the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction

- Place the point source in air within 1 cm of the center of rotation, set the radius of rotation to be approximately 15 cm, perform a acquisition using the matrix size and number of angles used clinically; collecting about 10K counts per view
- Reconstruct the data with filtered backprojection and ramp filter
- Perform a normal planar (static) acquisition at the home position, using the same acquisition condition as for the tomographic acquisition
- Repeat above steps with the point source placed about 8 cm off axis, and the
 point source placed on the axis of rotation, but close to the edge of the field
 of view
- Draw a profile through the image of the point source in the reconstructed image and calculate the FWHM in both the horizontal and the vertical directions

Tomographic resolution with scatter

Purpose

Check the tomographic resolution of the system in clinical conditions

Implementation

- Use resolution phantom with central hole filled with high specific activity ^{99m}Tc, place the center of the phantom within 2 cm of the center of rotation and close to the center of FOV
- Adjust the radius and collect data as the method described in the test of tomographic resolution in air
- Move the phantom so that its center is about 5 cm away from the axis of rotation and repeat above steps with a larger radius of rotation
- Draw profiles through the reconstructed image of the point source; both horizontally and vertically, then measure the FWHM, on the horizontal and vertical profiles

Slice thickness at center of slice

Purpose

 Teat the slice thickness to ensure that the spatial resolution along the tomographic Z axis is within limits

- The data is collected as the same method as for the test of tomographic resolution in air
- Locate the slice in which the point source is most clearly seen and locate the pixel in which the maximum number of counts is observed; Note the (X, Y) coordinates of this pixel and its maximum value
- Record the number of counts at this same (X, Y) pixel position for all slices adjacent to and including the slice in which the maximum was found, such that all slices containing counts of more than 5% of the maximum are included
- Generate a profile of the point source along the Z axis using these values, calculate the FWHM of this profile

Routine Test: Annually

Annually

- Collimator hole angulation
- Multiple window spatial registration

Collimator hole angulation

Purpose

 Check the septal alignment and angulation for all parallel hole collimators used

Implementation

- A point source is placed a few meters from the collimator, in the center of each parallel hole collimator and in four or more other positions approximately halfway to the edge of the field of view
- Acquired images should be visually inspected and checked for any asymmetries, streaks and distortions
- New collimator should be provided by the manufacturer if the collimator holes and septa do not aligned appropriately

Multiple window spatial registration

Purpose

 Ensure that the images acquired at different photon energies superimpose when more than one PHA is used simultaneously

- $-\,$ Remove the collimator and turn the head to face horizontally, a $^{67}{\rm Ga}$ point source is placed on a table adjacent to the scintillation camera
- The default PHA windows is set on the 93, 184 and 296 keV photopeaks and adjust the source activity not to exceed a count rate of 10,000 counts/s
- Acquire separate images through each of the PHA channels with 5,000K counts using the largest FOV available, and acquire an image with all three PHA channels contributing
- Position the source on the X+/X-/Y+/Y- axes of the detector face at about 75% of the distance from the center to the edge, remove the source and measure the distance between the two X and two Y source positions; also determine the coordinates of the X and Y source positions on each image, using count profiles or ROIs
- The locations at which the sources appear with the highest counts should coincide

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附件五、臨床核醫腦神經技術訓練教材

臨床核醫腦神經造影技術 訓練講義

臺北榮總核醫部編制

108年9月

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壹、 核醫造影檢查前置作業

- 一、臨床申請之檢查項目是否適當?
 - 1. 申請檢查項目,所提供臨床資料是否清楚?
 - 2. 臨床問題需求為何?
 - 3. 申請檢查項目是否真正能提供臨床有用的資訊?
 - 4. 假如有疑問需要澄清說明,可請教核醫醫師或研議委員會 (requesting party).
- 二、從事檢查的身份是否符合?
 - 1. 核對患者身份,名字是否完全相同
 - 2. 住院患者,核對病歷姓名、病歷號、性別、身份
 - 3. 記錄患者其他臨床相關檢查資料於申請單上
 - 4. 獲悉足夠的資訊,可協助報告的判讀
- 三、患者是否有何部位疼痛?
- 四、病歷是否有癌症病史記載?
- 五、是否成曾經手術?何種手術?何時?
- 六、患者身上是否有阻礙物(attenuators)?
 - 1. 如金屬皮帶頭或鈕扣
 - 2. 金屬項鍊
 - 3. 避免阻礙物造成假影最保險之方法是在檢查之前脫掉衣物, 穿上院方準備的袍子罩衫
- 七、是否有任何具有放射性物質在檢查前該移除?
 - 有些檢查放射製劑會從尿液排出,若此類患者以尿帶儲存, 則檢查前必須將尿帶移出儀器視野
 - 2. 如I-131全身掃描檢查,放射碘會自鼻黏膜、汗腺排出以致造成手帕污染,若污染手帕正好在視野內將會造成假影

- 八、近期是否曾作過任何核醫核種檢查,是否會干擾其他檢查?
 - 1. 若會干擾,延後檢查時間
 - 2. 若會干擾,急需檢查可提高注射劑量

九、患者是否懷孕?

- 1. 女性受檢者是否正值生育年齡
- 2. 除非她很確定無懷孕,所有女性患者皆需考慮可能懷孕
- 3. 若女性患者欲從事放射核種治療,應先接受懷孕試驗如beta-HCG·
- 4. 若女性患者確定或懷疑懷孕,核醫的醫師決定何種檢查應取 消或減少劑量

十、患者是否在授乳時期?

- 1. 如果受乳患者將接受檢查,應告誠終止受乳一段時間,等到確定嬰兒有效輻射劑量(effective radiation dose)小於0.1 rem(1mSv)。
- 2. 有關授乳建議如下表

服用放射製劑	劑量 (mCi/MBq)	建議停止授乳
Tc-99m-IDA	4.1/150	無需停止
Tc-99m-S-Colloid	2.7/100	無需停止
Tc-99m-Sestamibi	24.3/900	每天限制貼身接觸 5 小時
Tc-99m-PYP	16.2/600	停止餵奶 8 小時
Tc-99m-MAA	2.7/100	停止餵奶 18 小時
TC-99m-pertechnetate	2.7/100	停止餵奶 30 小時
Tc-99m-pertechnetate	21.6/800	停止餵奶 62 小時
Tc-99m-DTPA	16.2/600	停止餵奶 6 小時
Tc-99m-RBCs	21.6/800	每天限制貼身接觸 5 小時
Ga67-citrate	5.0/185	停止餵奶
I131-iodine	1.1/40	停止餵奶
I131-iodine	140.5/5200	停止餵奶

貳、 Tc-99m- TRODAT-1檢查說明書

一、什麼是Tc-99m-TRODAT-1腦部造影檢查?

Tc-99m-TRODAT-1腦部檢查,主要是針對腦多巴胺運轉器進行造影,影像可供醫師鑑別受檢者腦多巴胺運轉器活性及分布是否正常。

二、檢查流程與配合事項:

- 1. 請於約定時間前來注射Tc-99m-TRODAT-1藥物(提早10分鐘 到思源樓一樓核醫部櫃臺報到)。注射完Tc-99m-TRODAT-1 後,即可回病房休息或在院內自由活動,於約定時間再來核 醫部檢查(請一樣提早10分鐘報到)。
- 2. 腦部檢查約45分鐘,受檢者只需安靜平躺在核醫造影儀器上保持頭部不動即可;檢查過程中不會有任何的感覺,只有儀器繞著受檢者頭部轉動以收集影像訊號。
- 3. 為了避免影響檢查結果,受檢者前一天晚上8點後,到隔天下午檢查結束前,不可攝取含咖啡因的食物與飲料,若原先有服用醫師開立的交感神經興奮劑、麻黃素類鼻塞藥物或氣管擴張劑,請先停止服藥。待下午腦部造影結束後,即可恢復正常服藥,以確保檢查結果的正確性。
- 4. Tc-99m-TRODAT-1含有微輻射劑量,受檢者請暫時不要接近 孕婦及幼兒,約24小時後即可恢復正常。
- 5. 檢查結束後,可多喝水,以加速藥物排出。
- 6. 本檢查採預約制,若要更改檢查時間,請於前一天下午5:30 前來電更改。若當天未事先更改排程,受檢者檢查費用必須 重新計價。

參、Tc-99m-TRODAT-1造影檢查標準作業流程

- 一、此造影檢查臨床適應症:帕金森氏症為主
- 二、檢查禁忌:無
- 三、檢查前的準備:病患須注意檢查前停止服用含咖啡因之食物飲料或交感神經興奮劑、麻黃素類鼻塞藥物或氣管擴張劑等藥物。
- 四、注意事項: 檢查時間約50分鐘
- 五、檢查儀器:使用單光子電腦斷層掃描儀
 - 1. 選用準直儀 Collimator: Fan-beam or LEHR
 - 2. 檢查能窗選擇 Energy peak:140KeV 與 Window:15%

六、放射製藥

- 1. 藥物:Tc99m-TRODAT-1
- 2. 劑量:20 mCi
- 3. 給藥方式:I.V.

七、病患位置與視野範圍

- 1. 病患體位::SUPINE, 記得使用頭架造影
- 2. 視野範圍:BRAIN
- 八、儀器影像收集參數設定:選用單光子造影
 - 1. Matrix size:128×128
 - 2. Time per view:20 SEC
 - 3. DEGREES OF ROTATION:360(每個頭繞完 360 度)
 - 4. NUMBER OF VIEWS:120
 - 5. Zoom:1.23
 - 6. MODE:STEP AND SHOOT

九、檢查步驟及注意事項:

- 1. 給藥後等待時間:4 小時
- 2. 造影時間:50 分鐘
- 3. 將病人頭部固定在頭架上

十、影像處理參數設定:

- 1. 影像重建 Reconstruction: filter (Metz:cutoff:0.63, order:30)
- 2. 影像衰減校正(Attenuation correction):選用內建 Chang's method 做均勻化校正,使用 Manual 方式調整要校正(調整不同 Slice 的 ROI)
- 3. 利用 TRODAT _量化分析軟體分析 (如圖)

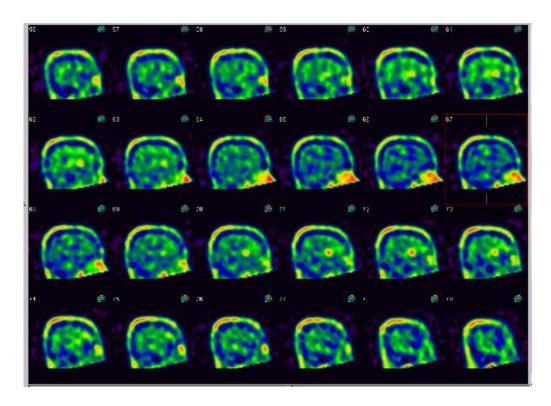
十一、影像報告格式 (附圖)

1. 基本提供影像判讀報告彩色三種切面,黑白三種切麵(影像 亮度以 Occipital 為 Base 藍綠色)

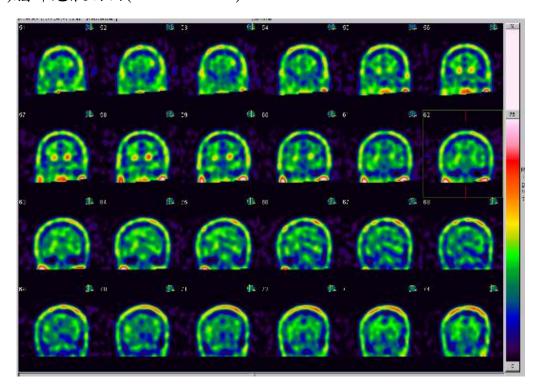
十二、備註:註明參考來源

 Tc-99m TRODAT-1 SPECT Imaging Protocol Guideline, Annals of Nuclear Medicine and Molecular Imaging(2016),29:45-53

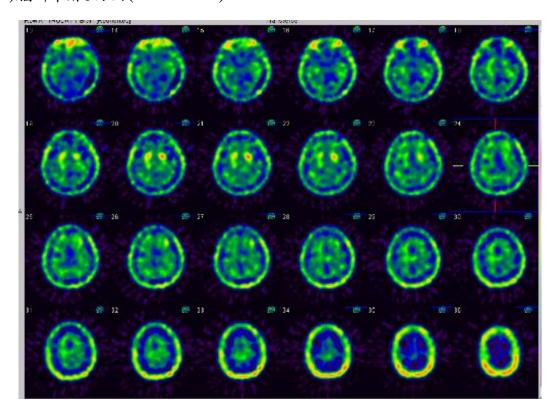
(A)腦部矢狀切面(Sagittal View)



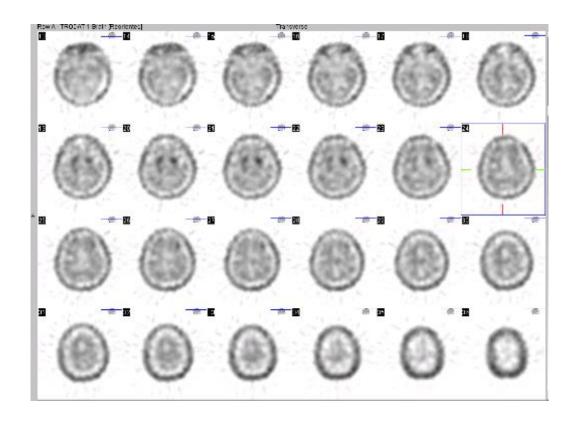
(B)腦部冠狀切面(Coronal View)



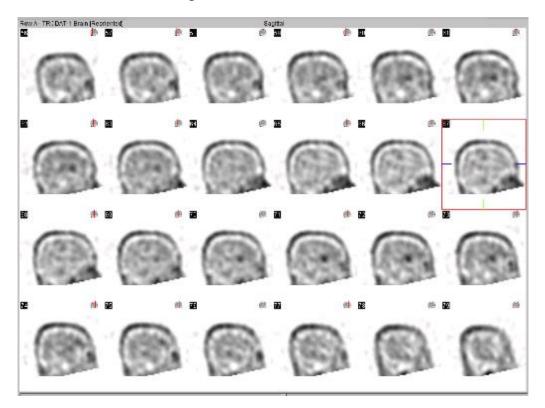
(C)腦部軸狀切面(Axial View)



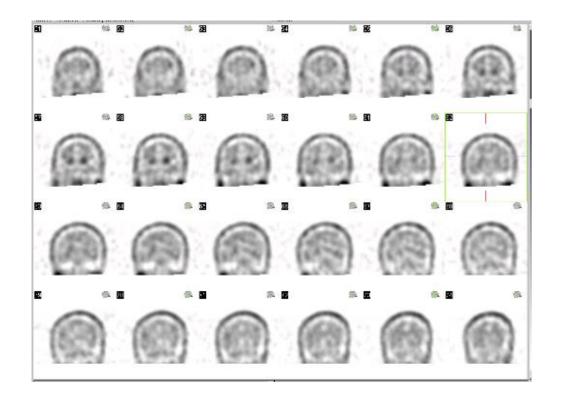
(D)腦部軸狀切面(Axial View)



(E)腦部矢狀切面(Sagittal View)

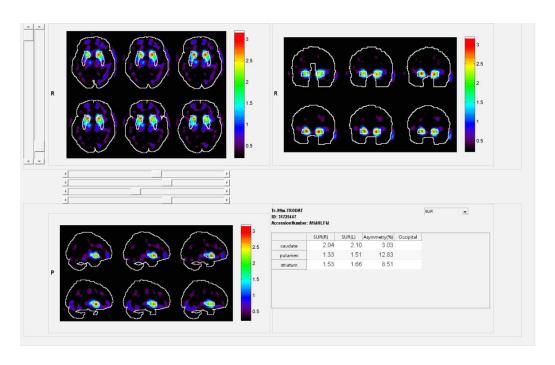


(F)腦部冠狀切面(Coronal View)



(G)腦部定量化軟體圈選,降低人為誤差,提供吸收藥物分佈數據

圖 2



肆、Tc-99m-ECD腦部灌注掃描檢查說明書

一、什麼是腦部灌流掃描?

利用放射性同位素製劑(Tc-99m-HMPAO或 Tc-99m-ECD)聚集在腦部皮質的特性,達到評估局部腦部血流之目的。

二、為什麼要接受這項檢查?

本檢查常用於下列用途,俾使病患獲得適當之醫療處置:

- 1. 找出可能的癲癇病灶,以評估手術治療的可行性。
- 2. 輔助診斷老人癡呆症(阿茲海默氏症)與其他癡呆症。
- 3. 腦血管病變、頭部外傷之評估。

三、檢查流程與配合事項:

- 若您懷孕或可能懷孕時,可能不宜接受本檢查,請事先告知櫃檯與醫療人員。
- 本檢查沒有特殊準備事項,受檢者可照常用餐,不必禁食, 生活作息如常。
- 3. 靜脈注射Tc-99m-HMPAO或Tc-99m-ECD 後,於安靜、光線 微弱之環境休息,通常經15-20 分鐘以上之藥物吸收後進行攝影。
- 4. 癲癇患者可於發作即時注射,待病人情況穩定後再進行攝

影。

四、可能的風險與副作用

- 1. 本檢查所使用同位素,非放射顯影劑,沒有顯影劑過敏的問題。
- 2. 注射後病患體內帶有少量輻射,因其含量甚低,不需特別防護。惟檢查當日可避免與孕婦、嬰幼兒長時間近距離接觸。 檢查後多喝水多排尿可加速部份輻射劑量排出。依據國內外 文獻及實際臨床經驗,本檢查之輻射劑量,幾乎不會增加致 癌機率,也不會增加不孕或後代異常的風險。

五、如果不想做這項檢查呢?

請與您的臨床醫師討論,考慮改採腦波圖、電腦斷層攝影、核磁共振造影、正子射出斷層攝影等其它可能之替代方案。

伍、Tc-99m-ECD 腦部灌注造影檢查標準作業流程

- 一、適應症:痴呆、癲癇、腦死、腦中風、腦梗塞
- 二、檢查禁忌:無
- 三、病患檢查前準備:檢查前1天避免服用咖啡因、酒及會影響腦 血流的藥物

四、注意事項:注射至造影完畢約1小時時間

五、檢查儀器:

- 1. 儀器名稱:單光子電腦斷層造影儀
- 2. 使用準直儀(Collimator): Fan-beam or LEHR
- 3. 影像收集能窗範圍(Energy peak): 140 KeV 與 Window:15%

六、放射製藥

1. 藥物:Tc-99m-ECD (或 Tc-99m-HMPAO)

2. 劑量:20 mCi

3. 給藥方式:I.V.静脈注射

七、病患位置與視野範圍

- 1. 病患體位:俯躺(SUPINE)
- 2. 視野範圍:腦部

八、單光子造影儀參數設定(ACO.Mode):

- 1. Matrix size:128×128
- 2. Time per view:20 SEC(每個投射收集 20 秒)
- 3. DEGREES OF ROTATION:每個機頭均繞行 360 度,避免假影產生
- 4. NUMBER OF VIEWS:120
- 5. Zoom:1.23
- 6. 掃描模式 MODE:STEP AND SHOOT

九、檢查步驟:

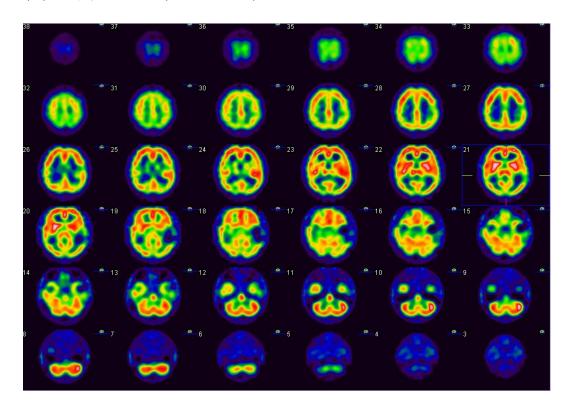
- 1. 給藥後等待時間藥物吸收大約 20 分鐘
- 2. 造影時間:大約需要45分鐘
- 3. 病人安靜平躺,並幫忙將頭部固定在頭架上,避免移動假影 產生
- 4. 儀器旋轉半徑請固定:設定約在 14-15 cm 之間

十、影像處理(參數設定):

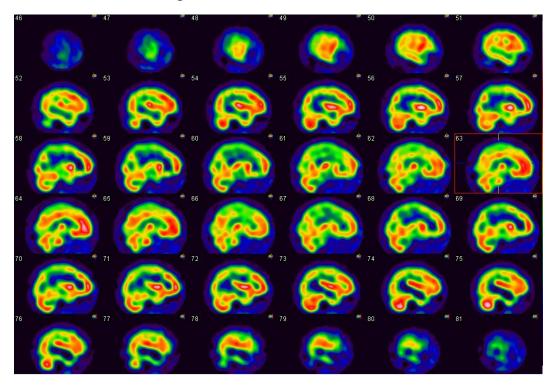
- 1. Reconstruction: filter(Butterworth; order 8 cut-off 0.4 cyc/cm)
- 2. Attenuation correction: Manual
- 十一、增加 EZIS 影像上傳(附圖)
- 十二、影像報告格式
- 十三、備註:註明參考來源

1. 參考來源:核醫造影技術手冊

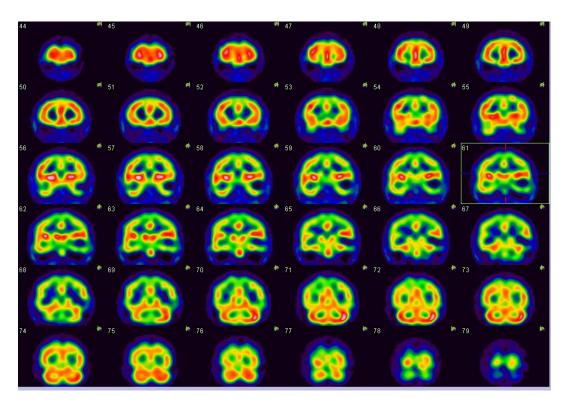
(A)腦部軸狀切面(Axial View)



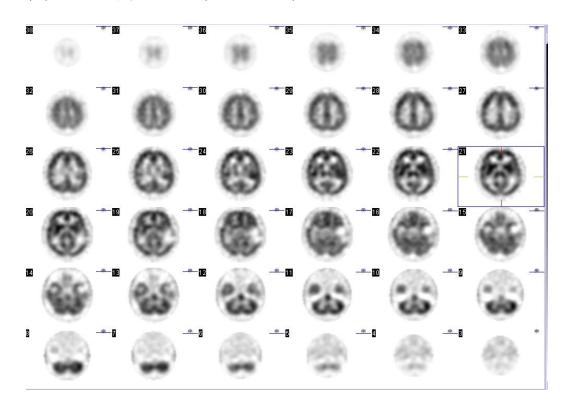
(B)腦部矢狀切面(Sagittal View)



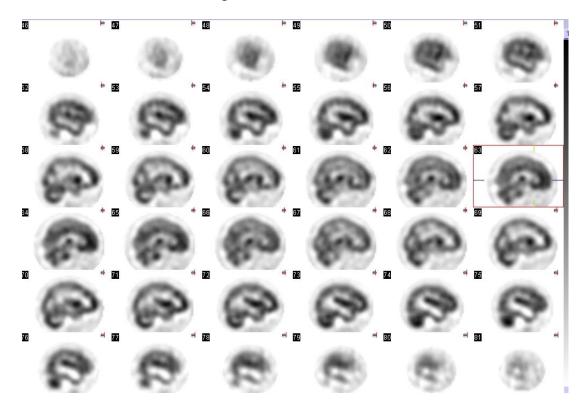
(C)腦部冠狀切面(Coronal View)



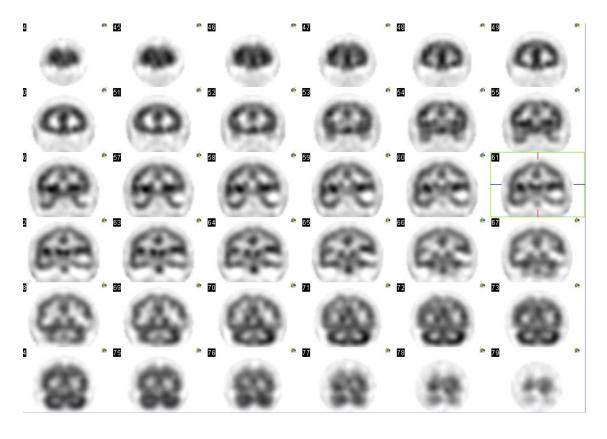
(D)灰階腦部軸狀切面(Axial View)



(E)灰階腦部矢狀切面(Sagittal View)

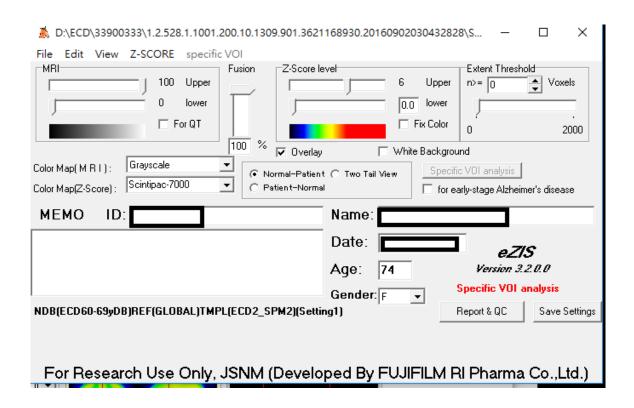


(F)灰階腦部冠狀切面(Coronal View)



(G)使用定量化分析軟體 EZIS,增加報告的標註。

- ◆ Patient-Normal Increase (blue to red)
- ◆ Two tail Increase (Red) Decrease (Blue)
- ◆ Norrmal-Patient Decrease (blue to red)



附件六、核醫影像品質保證國際論壇議程

2019 International Forum for Quality Assurance in Nuclear Medicine Molecular Imaging

Time: Jul 27, 2019 (W6)

Venue: Meeting Room, Department of Nuclear Medicine

Hosting: Department of Nuclear Medicine, Taipei Veterans General

Hospital(TVGH)

Time	Content	Chairman	Location	
08:30-09:00	8:30 a.m. meet at hotel lobby fo	Hotel lobby		
09:00-09:40	TVGH & Department of Nucl Prof. Wen-Sheng Huang, M.D. Med (NM) Introduction			
09:40-10:20	Visit the Department of NM, National PET/Cyclotron, and Translational imaging Centers Prof. Wen-Sheng Huang, M.D., Chief Technologist Prof. Bang-Hung Yang, and Chief Radiochemist Prof. Chi-Wei Chang		TVGH,	
10:20-10:30	Tea Break		Department of	
10:30-12:00	Quality Assurance and Nuclear Medicine Imaging Protocol: Worldwide Opinions	Nuclear Medicine		
12:00-12:30	Discussions and Group Photo All			
12:30-13:00	Lunch (lunch box provided)			
13:00-14:00	Travel to INER			
	INER and Division of Isotope Applications Introduction	Division Head Prof. Chih-Hsien Chang, and Vice Division Head		
	Visit Division of Isotope Applications, PIC/S GMP Radiopharmaceutical Manufacture Center, Preclinical Molecular Imaging and Radiopharmacology Center	Prof. Mei-Hsiu Liao, and Group Leader of Cyclotron Operations Prof. Ting-Shien Duh	INER	
16:30-17:00	Discussions and Group Photo Closing remark All			
17:00-18:30	Dinner & Farewell Party	1		

附件七、2019/11/25 開辦 Tc-99m-TRODAT-1 訓練課程表

99mTc-Trodat On-Site Interact Course

Date: Nov, 25, 2019 (Monday)

Venue: Department of Nuclear Medicine, Taipei Veteran General Hospital (VGHTPE)

Faculties: 1. Prof. WS Huang, M.D., Director of Dept. of NM & National PET/Cyclotron Center, TVGH

2. BH Yang, Ph.D., Team Leader of Radiologic Technologist, Dept. of NM & National PET/Cyclotron Center, TVGH

3. Yuan-Chung Wu, RadioPharmacist, Dept. of NM, TVGH



Siloam \$

Time	Content	Content Presenter Venu		Remark		
09:00-09:10	Opening	Prof. WS Huang, M.D.	VGHTPE NM center	9		
09:10-10:30	^{99m} Tc-Trodat-1 : Drug Preparation	Radiopharmacist, Wu	RadioPharmacy	Pharmacist Only		
09:10-09:30	Hospital Introduction	Prof. WS Huang, M.D.	NM Meeting Room			
09:30-10:40	99mTc-Trodat-1 SPECT : Clinical Application	Prof. WS Huang, M.D.	NM Meeting Room			
10:40-11:00	Tea Break	Tea Break				
11:00-12:30	99mTc-Trodat-1 Acquisition Protocol and Imaging Processing	BH Yang, Ph.D.	NM Meeting Room			
12:30-13:30	Lunch	All	NM Meeting Room	Lunch Box		
13:30-14:00	Quantitative Analysis of Striatum Image	BH Yang, Ph.D.	NM Meeting Room			
14:00-14:30	Imaging Discussion	Dr. Yudistiro	NM Meeting Room			
14:30-15:30	^{99m} Tc-Trodat-1 SPECT Scan with real patient	BH Yang, Ph.D.	SPECT Room	Real patient scan		
15:30-15:50	Tea Break					
15:50-16:45	99mTc-Trodat-1 SPECT : Read with Expert	Prof. WS Huang, M.D.	NM Meeting Room			
16:45-17:00	Q&A	All	NM Meeting Room			
17:00	Adjourn					
18:00	Dinner					

附件八、促成本院與澳洲雪梨利物浦醫院簽署合作備忘錄(MOU)



Date :

Memorandum of Understanding between Taipei Veterans General Hospital and Liverpool Hospital



MEMORANDUM OF UNDERSTANDIMNG ON ACADEMIC COOPERATION BETWEEN LIVERRPOOL HOSPITAL AND TAIPEI VETERANS GENERAL HOSPITAL

THIS MEMORANDUM of UNDERSTANDING (the "MOU") made and entered into as of 15th day of November, 2019, between Taipei Veterans General Hospital ("TVGH") with its office at No. 201, Sec. 2, Shipai Rd., Beitou District, Taipei City, Taiwan 11217, R.O.C., and Liverpool Hospital ("LH") with

The purpose of this MOU is to develop academic and educational cooperation and to promote

mutual understanding between the Nuclear Medicine Departments between the two institutions. Both institutions agree to develop the following collaborative activities in academic areas of mutual interest, on a basis of equality and reciprocity. 2

Exchange of faculty members, researchers, and administrative staff

its office at Corner of Elizabeth and Goulburn Streets., Liverpool NSW 2170, Australia.

(2) Implementation of collaborative research projects Implementation of lectures and symposia

(3) Exchange of academic information and materials

(5) Promotion of other academic cooperation on which both parties have agreed
The development and implementation of specific activities based on this MOU will be separately 3 negotiated and agreed on between the faculties, schools or institutes, which are to carry out the specific activities. Both institutions agree to carry out these activities in accordance with the laws and regulations of the respective countries.

It is understood that the implementation of any of the types of cooperation stated in Clause 2 shall depend upon the availability of resources and financial support at the universities/institutions concerned.

5 Should any collaborative research activities conducted under this MOU have any potential for developing intellectual property, both institutions shall seek an equitable and fair understanding

as to ownership and other property interests that may arise.

This MOU may be amended or modified by a written agreement signed by the representatives of 6 both institutions

This MOU is valid for a period of five (5) years from the signature date of the representatives of both universities/institutions below. This MOU may be renewed after being reviewed and renegotiated by both institutions.

This MOU may, at any time during its period of validity, be terminated by either university/institution upon prior written notice to the other party made at least six (6) months prior to the termination date.

The parties agree that this MOU is not a formal legal agreement giving rise to any legal

relationship, rights, duties or consequences, but it is only a definite expression and record of the purpose of the parties to which the parties are bound in honour only.

This MOU shall be executed in English in two (2) copies; each institution shall retain one copy.

Taipei Veterans General Hospital, Signed for and on behalf of Taiwan Liverpool Hospital Sydney Australia Superintendent General Manager Prof. Deh-Ming Chang M.D. Ph.D Ms. Karen McMenamin

(Signature)

(Signature) 2019

Date: Nov

本院與澳洲雪梨利物浦醫院簽署合作備忘錄(MOU)中文



Memorandum of Understanding between Taipei Veterans General Hospital and Liverpool Hospital



利物浦醫院和臺北榮民總醫院 (TVGH) 學術合作的合作備忘錄

本合作備忘錄(以下簡稱 "MOU")於 2019 年 11 月 15 日在臺北榮民總醫院("TVGH")其辦公室位於 11217 臺北市北投區石牌路二段 201 號及利物浦醫院("LH"),其辦公室位於 Corner of Elizabeth and Goulburn Streets., Liverpool NSW 2170, Australia.

- 1 合作備忘錄的目的是發展學術和教育合作,並促進兩個機構之間的核醫學部門之間相互了解。
- 2 雙方同意基於平等互惠的原則,就學術領域之活動進行合作,包括:
 - (1) 透過邀請貴我機構學者作短期參訪和/或教學以促進貴我機構之交流
 - (2) 執行共同合作研究計劃
 - (3) 實施講座和專題討論會
 - (4) 交換學術訊息
 - (5) 在雙方同意下促進學術合作
- 3 關於此合作備忘錄的執行,雙方的執行單位可以在雙方同意下訂定計劃案來落實,但需符合當地國的法律及規範。
- 4 上述活動應依可運用基金作財務規劃。
- 5 在此合作備忘錄下進行的研究,所產生的智慧財產或相關利益,由雙方平等的協商所有權的歸屬。
- 6 此合作備忘錄在利物浦醫院和臺北榮民總醫院負責人簽署修改函後,可修訂此合作備忘錄的內容。
- 7 此合作備忘錄在利物浦醫院和臺北榮民總醫院負責人,或其正式代表簽署後五年內有效,若雙方同意, 此一合作備忘錄可再延伸下一個五年。
- 8 任何時候若其中任一機構意圖終止此合作備忘錄,需在六個月前以書面通知到另一機構。
- 9 雙方同意該合作備忘錄不具任何法律關係,只是對雙方的目的的明確表述和記錄,僅以各方的名義受其約束。
- 10 兩份如本合作備忘錄製作成英文型式,並由臺北榮民總醫院及利物浦醫院各收執一份

Taipei Veterans General Hospital,	Signed for and on behalf of
Taiwan	Liverpool Hospital Sydney Australia
Superintendent	General Manager
Prof. Deh-Ming Chang M.D. Ph.D	Ms. Karen McMenamin
	okmumenamin
(Signatu	re)(Signature)
Date:	Date:

表一、東協核醫人才交流國外與會者名單

	國籍	姓名	職稱	任職機構
1	泰國	Yuthana Saengsuda	President	Nuclear Medicine Society of Thailand.
2	泰國	Sureerat Saengsuda	Radiological Technologist	Division of Nuclear Medicine, Department of Radiology, Rajavithi hospital
3	泰國	Achiraya Praisuwan	Professional Pharmacist	Lead GMP Inspector, Bureau of Drug Control, Thai FDA
4	泰國	Putthiporn Charoenphun	Pharmacist	Division of Nuclear Medicine, Department of Diagnostic and Therapeutic Radiology, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand
5	泰國	Thawi Yingsa-Nga	Radiologist	Division of Nuclear Medicine, Maharat Nakhon Ratchasima Hospital, Nakhonratchasima Province, Thailand
6	泰國	Mark Gallegos	Pharmacist	Thai GMS
7	泰國	Natthawuth Nainanont	Pharmacist	Thai GMS
8	泰國	Supakit Hluangjork	Pharmacist	Thai GMS
9	越南	Mai Trong Khoa	Formal President	Vietnamese Radiology and Nuclear Medicine Society
10	越南	Nguyen Dieu Ha	Deputy Director	Pharmaceutical Business Management Division, DAV
11	越南	Loc Thai Van	President	Vietnam Association of Radiological Technologists
12	緬甸	Kyin Myint	President	Myanmar Society of Nuclear Medicine
13	緬甸	Thet Zay Yar Myint	CEO	Radiance Infinity Co., Ltd. Singapore
14	印尼	Rini Shintawati	Medical Physicist	Nuclear Medicine Department of Hasan Sadikin Hospital Bandung Indonesia
15	印尼	Siti Masrochah	Radiographer, Lecturer	Radiological Technology at Health Politechnic of Semarang

表二、韓國外賓名單

	國籍	姓名	職稱	任職機構
1	1 韓國	Lee/ Won-Guk	Vice President	SAMSUNG MEDICAL
1				CENTER
2	2 韓國 1	Moon/Ill-Sang	Education Director	SEOUL NATIONAL
2				UNIVERSITY HOSPITAL
2	3 韓國	達國 Lee/Jong-Pil	Information Management	SAMSUNG MEDICAL
3			Director	CENTER
4	4 韓國 1	PARK / JUN MO	Radiological	YEOUIDO ST.MARY`S
4			Technologist	HOSPITAL
-	- 14	國 PARK / MIN HO	Radiological	SEOUL NATIONAL
5 韓國	報		Technologist	UNIVERSITY HOSPITAL
	韓國	PARK / JUN	Radiological	CEVED ANCE HOODEA
6 韓		YOUNG	Technologist	SEVERANCE HOSPITAL

表三、本部舉辦 Tc-99m-TRODAT-1 訓練課程印尼貴賓名單

	國籍	姓名	職稱	任職機構
	£n P	Dr. Ryan	Head of Nuclear	MDCCC Siloom Hoomitel
1	1 印尼	Yudistire	Medicine	MRCCC Siloam Hospital
2 印尼	۲n Þ	Ms. Desi	D 11 1	MDCCC Cileren Herrital
	Hutahaean	Radiographer	MRCCC Siloam Hospital	
3	印尼	Ms.Amelinda	Pharmacist	MDCCC Cile on Heavited
		Janice Herlina		MRCCC Siloam Hospital



圖一、東協核醫人才(泰國、越南、緬甸及印尼)參訪留影紀念



圖二、東協核醫人才臺北榮總中正樓大門前參訪留影紀念



圖三、主持人介紹台灣核醫現況,經驗交流講座



圖四、東協核醫人才參訪核能研究所留影紀念



圖五、 2019/11/16 台韓技術交流論壇合照留影





圖六、印尼 MRCCC 醫院醫師、放射師及藥師至本中心學習合影 留念。



圖七、本院張德明院長與澳洲雪梨利物浦醫院 Peter Lin 教授代表 共同簽屬學術合作交流協議書