行政院原子能委員會

委託研究計畫研究報告

亞太核醫醫藥法規與藥政制度研究

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目　錄

中文摘要

由於核醫藥品之特殊性，近年來已廣泛應用於診斷及治療疾病，台灣目前已是國際醫藥品稽查協約組織(PIC/S)及國際醫藥法規協和會(ICH)成員之一，配合行政院新南向政策及 5+2 旗艦計畫，將台灣優質核醫藥品推展至亞太國家，造福有需要之病人，惟因藥品上市前均須經法規單位確認安全、品質及療效後，方准予上市，因此研究亞太國家(泰國及越南) 確有其需求。

執行本次計畫方法如下

(1) 蒐集亞太國家(泰國、越南)核醫藥品的法規，發現亞太國家目前大都是依照目前現行的藥品管理法規管理，且並無專法法規加以規範管理，且大部分核醫藥品都採用醫藥先進國家認證方式。

(2) 七月二十六日假陽明大學膺才廳舉辦「“台灣 - 東協”核醫醫藥研討會」，其中邀約泰國食品藥物管理署與越南藥品管理局的官員來台與我國醫藥產業做深度的核醫藥法規交流。

透過前述方式執行本計畫後，得知目前在亞太國家(泰國、越南)核醫藥品的法上並無專法在執行；且在核醫藥物審核上，採用歐、美、日、台等先進醫藥國家審核過的藥品即可在該國上市使用。

故我們必須加速提升我國藥政法規符合國際化，培養與亞太區域藥政管理人才之良好互動，以期創造我國參與國際型藥政管理相關組織之機會，並強化生醫製藥產業國際競爭優勢。

英文摘要

Due to the special property of radiopharmaceutical, it has been broadly used in diagnosis and treatment. Taiwan has become the member of PIC/S and ICH, Taiwan's regulations and medicinal product has been recognized around the world. Also follow Executive Yuan New Southbound Policy and Biotechnology innovation project, to export Taiwan radiopharmaceuticals to Asia Pacific country will benefit needed patients. However, all medicinal product need to prove its safety, quality and efficacy before it launch to the market. Through collecting, analyzing regulations and hosting a forum and expert meeting to study Thailand and Vietnam regulations on radiopharmaceuticals will make this research project more complete.

The implementation of this plan is as follows

(1) collecting regulations on nuclear medicines in Asia-Pacific countries (Thailand, Vietnam), and found that most countries in Asia-Pacific countries are currently managed in accordance with current drug management regulations, and there is no specific laws and regulations to regulate and manage, and most nuclear medicines are certified by advanced pharmaceutical countries.
(2) On July 26, the "Taiwan-ASEAN" Nuclear Medicine and Medicine Symposium was held at the Yancai Hall of Yang-Ming University, inviting officials from the Thai Food and Drug Administration and the Vietnam Drug Administration to come to Taiwan and the Taiwan pharmaceutical industry. Do a deep exchange of nuclear medicine regulations.

After implementing the plan in the foregoing manner, it is known that there is no specific law in the laws and regulations on nuclear medicines in Asia-Pacific countries (Thailand, Vietnam); and in the audit of nuclear medicines, Europe, the United States, Japan, Taiwan, etc. are adopted. Drugs reviewed by advanced medicine countries can be listed in the country.

Therefore, we must accelerate the improvement of Taiwan's drug and government regulations in line with internationalization, and cultivate good interaction with the pharmaceutical administration talents in the Asia-Pacific region, with a view to creating opportunities for Taiwan to participate in international drug administration-related organizations, and to strengthen the international competitive advantage of the biomedical pharmaceutical industry.

壹、 計畫緣起與目的

一般而言用的適當是藥品，用的過量即毒藥。是以世界各國均對藥品有一連串嚴格的上市前審查，待確認產品安全、品質及療效後，方准予上市提供民眾及病人使用。當然在具有放射性質的核醫藥物亦無法例外；因此，在藥政管理上，法規單位會對核醫藥物訂定專屬法規。由於核醫藥物的專一性與獨特性，且常會與特定組織結合，搭配儀器進行偵測，尤其近年來廣泛應用於疾病診斷及癌症、神經科或其他疾病之治療。

一、 國際現況

美國對於核醫藥品之管理除依循一般藥品之管理法規及概念外，亦訂有放射性藥物臨床評估指南(Guidelines for the Clinical Evaluation of Radiopharmaceutical Drugs)，基於產品短半衰期特性，對於部分經州政府認證之放射性藥物(nuclear pharmacy)於2018年9月公布國家許可核藥房和聯邦設施工業指南對放射性藥物的調製和重新包裝基準(Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities)，此外在美國藥典(USP General Chapter) 823亦訂有藥品優良製造規範（cGMP）相關規範，在世界各國管理是相對嚴謹但又有彈性。

歐盟對於核醫藥品之管理，是在歐洲藥品管理局(EMA, European Medicine Agency)人用藥品委員會(CHMP)下設置放射性藥物起草小組(Radiopharmaceuticals Drafting Group)，專職起草核醫藥品相關法規基準，每年訂有年度工作目標，透過面對面及視訊會議等方式進行，歐盟的核醫藥品法規之法源為65/65/EEC 指令, 75/318/EEC 經修正後指令, 89/343/EEC 指令最早在1990年12月即被各國採認，並

自1991年6月生效，另由歐洲藥品管理局訂定上市審查基準則是在2008年11月26日公告，並自2009年5月1日生效。參考國際醫藥法規協和會及相關規範管理在歐盟上市之核醫藥品。

二、 台灣現況

台灣的醫療水準與醫藥產品在國際上廣受認可，目前台灣亦是國際醫藥品稽查協約組織及國際醫藥法規協和會的成員國之一，不論在製造或法規管理均與國際接軌，在核醫藥品方面，國內亦有核研所、研究單位及醫療機構進行核醫相關新藥的研發。經查詢衛生福利部許可證資料庫，截至108年2月底共核准核醫藥品許可證計59張，其中國產許可證共20張，而核研所持有之許可證即佔了16張，這些藥品除可提供國內臨床醫療使用外，亦可將產品推廣至國際市場，給更多需要的病人使用，因此，研究各國對於核醫藥品上市管理規範確有其需要，亦為本研究計畫的主要緣由。

台灣對於核醫藥品的管理，主責機關為衛生福利部食品藥物管理署(以下稱食藥署)，參考歐美管理模式，採取全生命週期管理概念，上市前須經查驗登記程序，製造廠亦須符合國際醫藥品稽查協約組織的藥品優良製造規範方得核准製造上市，新藥還須經過臨床試驗程序；對於核醫藥品之管理我國食藥署除依循一般藥品管理原則外，並於1999年5月14日公告核醫放射性藥品臨床試驗基準；1999年10月15日公告核醫放射性藥品審查基準；且於2003年12月29日公告斷層掃描用正子放射同位素調製作業要點(2018年7月16日預告修正草案中)，提供核醫藥品臨床醫療上需要。

三、 新南向政策

蔡英文總統於105年 5月20日就職後提出新南向政策，並於8

月 16 日公布「新南向政策」政策綱領[1]，啟動我國重新定位國家在亞洲發展重要角色，尋求新階段經濟發展新方向與動能，創造未來價值的重要經貿戰略。總體長程目標之一為：促進台灣和東協、南亞及紐澳等國家的經貿、科技、文化等各層面的連結，共享資源、人才與市場，創造互利共贏的新合作模式，進而建立「經濟共同體意識」。後續搭配五大旗艦計畫及 5+2 產業，期落實新南向政策，其中醫衛合作在衛福部一國一中心積極推動下已有初步成果，透過台灣醫療結合產業南進，榮陽團隊與越南相關單位已初步建立合作管道，期能達到貨出去錢進來的效益。惟如同前面所說藥物上市前須經審查程序，所以研究南向國家醫藥法規，再研擬策略方能達到將產品推到南向國家之最終目標。過往國內衛生主管機關僅對歐美管理法規進行研究，並未就越南及泰國等東協國家之核醫藥品上市法規與市場現況進行相關研究，因此，本計畫將成為首個研究越南及泰國核醫藥品管理法規的計畫。經由本計畫之執行，除可進一步了解東南亞國家對於核醫藥品管理法規現況外，也配合行政院新南向政策，協助有意願將國產核醫藥品行銷至東南亞國家之業者，作初步之評析，同時培育國內製藥法規人才掌握東協國家對於核醫藥品管理趨勢。

[1] 2016 年 8 月 16 日蔡英文總統召開對外經貿戰略會談，通過「新南向政策」政策綱領。

貳、 研究方法與過程

本次的研究目的為配合國家南向政策，將以東協十國中的越南以及泰國這兩個國家為主，蒐集該國在核子醫學方面的相關法令並加以分析比較與台灣現行的法規上的差異性，用以提供給目前國內有意願前往東協的國家發展的生技相關產業一個依據。

一、 我國核醫法規

我國核醫放射藥品相關法規以衛署88年公告「核醫放射性藥品臨床試驗基準」及「核醫放射性藥品審查基準」為主。此二基準參考美國於1981年公告的放射性藥物臨床評估指南(Guidelines for the Clinical Evaluation of Radiopharmaceutical Drugs)，並參考當時我國核醫放射藥品輸入與開發背景所訂定。早期核醫放射藥品多為歐美已核准之藥品或放射核種與未標幟部份具豐富人體使用經驗之新藥，一般用於診斷用核醫放射藥品劑量較低，且多為一次性注射。依其是否具藥理作用分為三級，各有不同之非臨床試驗法規要求，但皆較一般小分子藥品簡單。目前我國國內已核准的核醫藥品許可證計有57張，其中國內自行生產的有20張，國外進口的有27張。

近年國內法人研發機構及藥廠紛紛投入新一代診斷用核醫放射藥品的研發，融入精準醫療的概念，提升診斷用藥之標靶特性，甚至使用抗體或短鏈胜肽作為未標幟部份。且治療用核醫放射藥品，國內開發或查驗登記的經驗較少，由於達到藥理療效所需之輻射劑量及投予頻次高於單一使用之低劑量診斷核醫放射藥品，在法規考量上與其他小分子藥物並無差異，且須提供輻射劑量相關安全性報告。故國內在此部分法規仍需加強，可參考歐美相繼預告將針對核醫放射藥品非臨床試驗增訂新的規範，例如歐盟人用醫藥產品委員會於2017年7月公告「放射性藥物的非臨床評估中關於製定指導意見文件」(Concept paper on the development of guidance on the non-clinical evaluation of radiopharmaceuticals)；及美國食藥署亦於2017年9月公告

「微量放射性藥物診斷藥物：非臨床研究建議」(Guidance for Industry：Radiopharmaceutical Diagnostic Drugs：Study Recommendations)草案。

二、 東協核醫法規

東協依照 1999 年 3 月的會議於同年 9 月在馬來西亞成立東協標準和質量協商委員會藥品工作小組(ACCSQ PPWG)，其目標是調和東協各成員國藥品法規，並以補充和促進東盟自由貿易區，在以不影響藥物質量，安全性和有效性前提下，消除因各國在藥品不同的法規所帶來的貿易技術壁壘。

該藥品工作小組於 2016 年 12 月依照國際醫藥法規協和會的電子通用技術文件（ECTD）標準，制訂了東協通用技術文件(ACTD)，並依照(1）建立透明的監管程序、（2）規範監管要求以及（3）取消需要重複研究以滿足各種法規要求，從而使製藥公司有更多的時間和資源可用於研究和開發新藥三點。制定東協藥品的倡議，且因東協各國遵守此倡議，將使所有東協國家在藥政有一個統一的監管政策。

而迄至今日東協藥品工作小組業經十三次會議，但並未有一次會議針對核醫部分提出討論進而制定專門法規。故大大增加本計畫的蒐集法規資料的難度，為此本次計畫先行針對越南與泰國先行嘗試蒐集相關法規資料，經過查詢越南藥品管理局與泰國食品藥物管理署（TFDA）內的法規，發現同於台灣民國 88 年前一樣，國家尚未針對核子藥物部分有專法。

另外關於法規部分，有蒐集到相關的應該的是亞洲核合作論壇(Forum for Nuclear Cooperation in Asia)，所提出的亞洲各國在「工業/環境和醫療保健利用」合作指南，中有提出相關於輻射在醫學利用發展的部分，但其符合的是核能使用上的法規，非屬於醫藥上的專法。

（一） 泰國現況

管理藥品方面是由泰國 FDA（Thia-FDA）負責，該部門是公共衛生部（MPH）下屬的幾個機構之一，是泰國管理藥物的監管機構，負責上市前控制，上市後控制和不良影響監測。藥物管制局根據“藥物法”管制藥品，所有藥品和製藥公司的註冊，許可，監督，檢查和不良事件監測。外國製藥公司主導泰國藥品市場。部分由於貿易談判，區域協調和積極的經濟趨勢，預計到 2022 年泰國的醫藥市場將翻一番。目前有幾個版本的“藥物法”生效，泰國政府正在製定修訂版，並附有更新的法規。根據現行法律，藥品被分類為傳統藥品或現代藥品，具有不同的應用和監督。現代藥物分為三類，每類都有單獨的註冊要求。

關於泰國核醫藥的演進過程，是由曼谷瑪希隆大學 Siriraj 醫院放射科的 Romsai Suwannik 教授(譽稱為泰國核醫學之父)在 1955 年於泰國建立了第一個核醫學科。在泰國核醫學早期是在 Siriraj 醫院的 Romsri Suwannik 教授利用膠體金（^{198}Au）進行臨床核醫學，用於治療由卵巢癌引起的腹水。之後進行了許多放射性核素非成像研究，包括血容量研究，^{51}Cr 紅細胞（RBC）存活和 ^{59}Fe 的鐵動力學研究，^{51}Cr 血小板存活和 ^{125}I 標記的纖維蛋白原的動力學研究，^{55}Fe 和 ^{59}Fe 吸收研究，以及使用 ^{99m}Tc-DTPA、^{131}I- hippuran 進行腎功能評估等研究。

1982 年泰國核醫學會在 Romsai Suwannik 教授催生下成立，有 120 名成員，由 1982 年迄今在許多核醫學人員為泰國的核醫學服務發展做出了巨大貢獻。加上國際原子能機構（IAEA）贊助英國、澳大利亞、美國、荷蘭、日本、法國、瑞典與印度等國家的核醫學專家

提供臨床服務和研究中引入了新技術與核醫學培訓，改善泰國的核醫學服務和研究方面，使得泰國在核醫藥的進步。

目前，25 個組織在泰國提供臨床核醫學服務。其中有五個醫學院提供三年核醫學住院醫師培訓，八家公司提供放射性藥物和/或核醫學設備。其中一個學院是由泰國原子能和平辦公室（泰國的 OAP）直接管理。

泰國的核醫學研究和臨床實踐近年來有了很大的改進，並將在不久的將來取得更多進展。這些成就有助於 ARCCNM 和亞洲國家在這一科學領域的進步。

（二） 越南現況

越南的主要監管機構是衛生部（MOH）和越南藥品管理局（DAV）。2013 年，衛生部授權省衛生廳為外商獨資企業的藥品生產，藥品維護，藥品檢測和藥品進口證書。

越南的監管環境往往不明確且不一致。法規通常根據具體情況實施，幾乎沒有整體協調。大部分產品應用程序可以用英語完成。藥品申請包所需的文件包括：來自原產國的免費銷售證書，GMP 認證，產品信息，製造過程的詳細描述，質量規格，成品樣品，包裝信息，包括越南語插頁傳單等。在申請審查和批准後，批准許可證（當地稱為簽證)過程的時間表大約為六個月，但是，藥物批准時間有所不同，可以預期延誤。為了控制藥品價格上漲，越南政府要求藥品進口許可證披露產品價格。本地專業知識有助於避免或限制政府價格限制。

三、 法規比較

法規蒐集結果不論是在越南與泰國，還是東協的藥品工作小組對於核醫方面目前皆尚無特定的法規；是以東協內對於核子醫學藥物目前仍屬於在醫院內自行管理部分，其餘有關於藥物法規部分的申請同於一般藥物的法規皆使用東協通用技術文件格式送件，並無另外設置專法監管。

（一） 法規

我國對於新藥查驗登記/註冊的規定來自藥事法第 39 條的規定：「製造、輸入藥品，應將其成分、規格、性能、製法之要旨，檢驗規格與方法及有關資料或證件，連同原文和中文標籤、原文和中文仿單及樣品，並繳納費用，申請中央衛生主管機關查驗登記，經核准發給藥品許可證後，始得製造或輸入。」亦即廠商須向食藥署申請藥品查驗登記獲核可，並發給藥品許可證後，始得於國內販售該項藥品。至於核醫醫藥部分根據藥品註冊管理條例第 43 條為主，其中關於放射性藥物註冊與放射性藥物之藥物申請部分，除須一併提交申請外且申請應符合中央衛生主管部門公佈的「核醫放射性藥品臨床試驗基準」和「核醫放射性藥品審查基準」。本章規定的新藥規定也適用於新劑量的放射性藥物。註冊放射性藥物所需文件包含藥物描述、規格、非臨床動物研究報告、臨床試驗報告及輻射劑量研究報告，有關各種應用的詳細要求。

泰國對於藥品查驗登記的規範來自藥事法(section 99, Drug Act BE 2510 (AD 1967)，主要由公共衛生部（MOPH）監管，泰國食藥署則會監控核醫藥申請所有文件，包含臨床前期及臨床試驗結果、營銷許可證、新藥申請文件以及新藥生產文件。至於核醫醫藥法規部分上

除需要經過泰國食藥署核可外，還需經過泰國原子能和平辦公室(OAP)審核通過的「使用放射性物質許可證」，方可製造或輸入。

越南藥品管理法規，主要是遵從其政府訂定之《藥事法》，並配合藥事法於2005年由其法務權責機關發布施行，係依據藥事法制定，相當於台灣首次在民國62年(1973年)頒布之《藥物藥商管理法施行細則》， 並於民國83年(1994年)配合台灣藥事法修正，更名為《藥事法施行細則》。此外，越南關於核醫醫藥法規部分，是根據放射性藥物交易的條例第34條，任何有關放射性藥物交易之企業必須取得藥房管理局書面批准並符合政府規定。放射性藥物製造商其材料與生產設備應為GMP製造工廠，並具有進行輻射工作的許可證，且儲存放射性藥物的獨立倉庫需符合GSP要求的分離區域。

（二） 流程

台灣之藥品註冊審查由衛生福利部食品藥物管理署(TFDA)主司，申請人向TFDA提出申請案，TFDA收案後，先進行行政審查， 而後委請財團法人醫藥品查驗中心(CDE)進行技術性審查。CDE 對於審查結果可建議「准予登記」或「不准登記」，再交由TFDA裁決，最終結果由TFDA通知申請者，申請者如對結果不服， 可提供資料並敘明理由，提出申復。因此，藥品的註冊，無論是台灣在地生產製造，或是由國外進口，皆是向TFDA提出註冊申請。

在泰國方面，則是向 Thai FDA 的 One Stop Service Center 提出申請，泰國和台灣不同之處在於僅接受紙本送件，經過行政前文件審查後，會進行分案，技術部分將交由外部審查委員，而在審查費用方面， 台灣須在提出查驗登記申請時交審查費用，而泰國政府規定，廠商提交藥品許可證申請時不須付費，藥品許可證核發後才須付費，

藥品進口許可證的政府費用為每年 10 萬泰銖，藥品註冊的政府費用為每個案子 2000 泰銖 ，沒有續訂費，此規定以及低廉的審查費用易造成廠商大量送件，官員審核量相較台灣來的大，人力吃緊，因此往往無法達到所規範之審核時程，另外，在泰國，有需要補件狀況時，廠商要 6 個月內提出， 補件後 BPOM 有 100 天的審閱期限 ，再回覆廠商。整體而言，泰國新藥的審核流程約 2 年，學名藥的審核流程約 1.5 年，相較於台灣最長的一年時間來說大約有兩倍差距左右，對於分秒必爭搶上市的藥品產業， 算是一段相當長的時間。

越南部分，其主要監管機構為越南衛生部（MOH）和越南藥物管理局（DAV）。2013 年，越南衛生部授權省衛生廳頒發外資企業藥品製造、藥品檢測和進口之藥證。然而相較於其他東協各國， 越南政府對藥品註冊審批之制度仍屬尚未健全，其監管環境往往不清楚及不一致。雖然最高規章為越南政府訂定之藥事法為基礎，但許多執行上仍以個案基礎實施，法規的健全與協調性仍待建置。 以目前越南 DAV 核發藥證的審閱期約為 6 個月，但實際情況仍視當地審核程序而定。值得注意的是，台灣對於進口藥品之審查，無論在學名藥方面、新藥方面或是新藥臨床試驗方面，均與國產藥品無流程上的區隔。但越南由於目前法規仍待完善，尚須透過兩國談判與實際視訪才有利保障國內藥廠赴越南投資利益之維護。

參、 “台灣 - 東協”核醫醫藥研討會

一、 緣起

為配合政府新南向政策，並協助我國核醫製藥產業了解東協最新藥政資訊及加強與東協國家藥政主管機關專家之交流，行政院原子能委員會核能研究所於 108 年 7 月 26 日委託國立陽明大學舉辦第一屆“台灣 - 東協”核醫醫藥研討會「2019 Taiwan-ASEAN Nuclear Medicine Forum」。以台灣、東協各國的核子醫放射藥品的發展與法規作為今年度主題。

二、 活動介紹

為了協助我國在核醫製藥產業了解東協各國藥政管理制度，本研討會特邀請泰國與越南的藥政主管機關代表與核醫學會的理事來台分享該國最新藥政管理現況、醫藥法規協和化的最新進展與核醫藥目前的發展狀況與前景，進行多國交流，用以促進我國與東協核醫藥的產官學界了解。並藉由此研討會加強我國核醫醫藥產業對於東協最新藥政現況與未來趨勢之認知，創造我國核醫製藥產業之國際競爭優勢，並推廣我國核醫藥品之國際市場，以期打開東協的核醫藥品通路。

- 主辦單位：行政院原子能委員會核能研究所 Institute of Nuclear Energy Research (INER)
- 承辦單位：國立陽明大學藥物科學院 (National Yang Ming University)

- 活動網址：http://web.phs.ym.edu.tw/tanm/
- 活動海報：

- 活動時間：108 年 7 月 26 日上午 9:00 至 下午 5:00
- 活動地點：陽明大學守仁樓膺才廳

三、 邀約來台之東協代表資訊

國家	姓名 Name	職稱 Title	單位	聯絡方式
泰國	Achiraya Praisuwan	Professional Pharmacist, Lead GMP Inspector	Bureau of Drug Control, Thai FDA	e_inkkajoo@hotmail.com
泰國	Yuthana Saengsuda	President	Nuclear Medicine Society of Thailand.	yuthanasae@yahoo.com
泰國	Sureerat Saengsuda	Division of nuclear medicine	Division of nuclear medicine, department of radiology, Rajavithi hospital	sureeratsae@hotmail.com
泰國	Putthiporn Charoenphun	藥學博士	Division of Nuclear Medicine, Department of Diagnostic and Therapeutic Radiology, Ramathibodi Hospital	ps4436@hotmail.com
泰國	Thawi Yingsa-Nga	醫師	Division of Nuclear Medicine, Maharat Nakhon Ratchasima Hospital , Nakhonratchasima Province, Thailand	thawi.ying@gmail.com
越南	Mai Trong Khoa	Formal President	Formal President of Vietnamese Radiology and Nuclear Medicine Society	khoa.maitrong@gmail.com
越南	Nguyen Dieu Ha	Deputy Director	Pharmaceutical Business Management Division,DAV	hand.qld@moh.gov.vn
越南	Loc Thai Van	越南放射師公會會長	President of Vietnam Association of Radiological Technologists	thaivanloc@hotmail.com
緬甸	Kyin Myint	President	Myanmar Society of Nuclear Medicine	kmnumed@gmail.com
緬甸	Thet Zay Yar Myint	CEO	Lucky Charm Co, Ltd. Singapore	tzymyint.biz@gmail.com
印尼	Rini Shintawati	放射師	Nuclear Medicine Department	rshinta70@gm

國家	姓名 Name	職稱 Title	單位	聯絡方式
			of Hasan sadikin hospital Bandung Indonesia	ail.com
印尼	Siti Masrochah	放射師	Nuclear Medicine Department of Hasan sadikin hospital Bandung Indonesia	masrochah2@gmail.com

四、 邀約講者資訊

邀請國內與東協國家(越南、泰國與緬甸等三國)的官方與核醫醫藥相關代表分享各國藥政管理現況，與各國核醫藥品的使用與發展狀況，藉此討論我國核醫藥品產業於東協各國投資經營、產品行銷規劃與國際合作模式，透過東協組織成員國專家之討論分析國際協和化最新合作現況，強化我國核醫藥政管理體系與國際接軌。

場次	分類	照片	姓名	職稱	單位
上午 第 1 場	國內		Professor Ruoh-Fang Yen	President	Nuclear Medicine Society of Taiwan.
	摘要： The utilization of nuclear medicine (NM) studies in Taiwan is greatly influenced by the reimbursement of Taiwan's National Health Insurance (TNHI), which started in 1995. Although functional and molecular characteristics of nuclear medicine imaging can provide important diagnostic information of diseases, the nuclear medicine scan is not as popular as CT and MRI. Nevertheless, depends on the clinical need and the availability of radiopharmaceutical, some of NM scan increases steadily but some decreases gradually. From the database of TNHI, we notice that whole body bone scan, myocardial perfusion imaging and whole body PET imaging were the top three most frequent NM imaging in Taiwan. On the contrary, the utilizations of Meckel's diverticulum scan, renal scan, and lung ventilation study are significantly decreased. The number of single photon studies were 13714 per million population and PET scan were 924 per million population (6.3%) in 2012. Tc-99m radiopharmaceuticals contribute for about 67% while Tl-201 chloride contributes for about 25% of all NM studies. As for PET tracers, Flobetaben, an F-18 amyloid tracer is the only PET tracer which has license				

from TFDA besides F-18 FDG at present. Other PET drugs, such as F-18 NaF, F-18 FDOPA, F-18 FLT, F-18 FCH and C-11 acetate, have been approved for clinical use according to the Regulation for Manufacturing and Compounding of PET Radiotracers, of which the first version was published on 2003. Other PET tracers use in clinical trials include amyloid (C-11 PiB, Flobetapir), tau (F-18 T807), Ga-68 DOTATOC (SSRT), Ga-68 PSMA (prostate cancer), etc.

國內		Mei-Chen Huang	Section Chief	Taiwan FDA

摘要：

Radiopharmaceutical products are regulated under the same regulatory framework of other pharmaceutical products: the manufacturing, distribution and registration are regulated under the Pharmaceutical Affairs Act, and the clinical use is regulated under the Medical Affairs Act. Consultation system and expedite review pathways are also applicable for radiopharmaceutical products. However, with the special characteristics of radiopharmaceutical products, TFDA has developed specific guidelines and review requirement defined in the Regulation for Registration of Medicinal Products following international standards. Currently there are 56 radiopharmaceutical products licensed in Taiwan, one third of them are locally manufactured. On the other hand, 88% of the licensed radiopharmaceutical products are for diagnostic purpose, only 12% are for treatment use.

Positron Emission Tomography (PET) radioisotopes have a very short half-life, so the transportation is a big limitation, especially long distance. In order to meet the great amount of the demands of different PET radioisotopes, compounding of PET radioisotopes is allowed in 9 certified PET centers in different hospitals in Taiwan except for supplying by the pharmaceutical company. To ensure the quality of the compounded PET radioisotopes, the whole compounding process and the quality management need to be in compliance with the Direction and Guideline

<table>
<tr><td></td><td colspan="5">for PET Radioisotopes Compounding.</td></tr>
<tr><td rowspan="2">上午
第 2 場</td><td>泰國</td><td>  </td><td>Professor
Yuthana
Saengsuda</td><td>President</td><td>Nuclear Medicine
Society of Thailand</td></tr>
<tr><td colspan="5">摘要：
Nuclear medicine in Thailand started in 1955. Professor Romsai Suwannik at Siriraj hospital was the first person to use radioisotope for medical care by using colloidal gold for palliative treatment of ascites with tumor seeding in the peritoneal cavity of advanced ovarian cancer to relieve pain and suffer. Later, radioactive iodine was introduced for diagnosis and treatment of toxicgoiter and thyroid cancer. The following sites of NM facilities were in Chulalongkorn, Rajavithi and Chiangmai hospital respectively. Nuclear Medicine Society of Thailand was established in 1982 with 120 members and Professor Romsai Suwannik was elected as the first president. At present, this organization consists of 300 members including 90 nuclear medicine physicians and the rest are technologists, physicist, radiochemist, radiopharmacist, nurse. There are 2 regularly academic meetings for society members in March and December each year.
Nuclear medicine in Thailand accomplished a step by step of progression and development in equipment and technology, clinical practice in term of diagnosis and treatment and research activities. Now, Thailand has 29 nuclear medicine centers: 16 in Bangkok, 3 in north, 4 in northeast, 2 in east, 2 in central part and 2 in south. 27 SPECT gamma camera, 16 SPECT/CT gamma camera and 10 bone densitometer are available in nuclear medicine centers for service. There are 11 PET CT machines with 8 machines in Bangkok, 3 in provinces, 4 cyclotrons of medium energy with 3 in Bangkok (Chulabhorn, Siriraj and BDMS hospitals) and 1 in Chiangmai. Rosatom (Russia) will supply a fifth cyclotron complex 30 MeV at Thailand institute of nuclear technology (TINT) with the government project 2018-2021 at Nakhon Nayok province.</td></tr>
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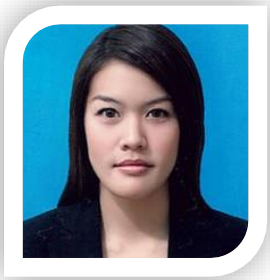
	Thai population are 69 millions with the rate of one PET/CT is for 6.27 million population. Nuclear medicine residency training started in 1989 with 5 university medical institutes for 3 years training course. Residents have to pass the exams to get Thai board of nuclear medicine set up by Thai board committee of nuclear medicine and under Royal College of Radiologist of Thailand. Consequently, 62 residents were trained up to date. At present, World Federation of Medical Education (WFME) standard of quality improvement in post graduate medical education in Thailand is settled in nearly all specialty including nuclear medicine of residency training. At the moment, all 5 nuclear medicine residency training centers have been accredited for WFME standard by national auditor team. For nuclear medicine 59455 studies in the year 2016, the top five studies are bone scan 47.5%, total body scan (I131) 12.3%, cardiac scan 11.3%, PET oncology 9.3% and thyroid scan 7.5% which are composed of 87.9% . For 12338 radionuclide therapy among all centers, the two most procedures are I131 treatment in hyperthyroidism 70% and thyroid malignancy 29%. The rest 1% procedures are in I131 MIBG treatment, Sm-153 EDTMP, Ra-223, Y90 microsphere, etc. Up-to-date, theranostics in nuclear medicine is in the beginning period using targeted radionuclide therapy in prostate cancer and neuroendocrine tumor among university nuclear medicine centers with promising results. The nuclear medicine society of Thailand have signed an MOU with the nuclear medicine society of Japan since October 2016 for mutual exchange of education and research activities. It is also a great step for academic collaboration between two countries, Taiwan and Thailand, to have an MOU with each society of nuclear medicine in 2017 as well as MOU between INER and faculty of medicine, Chulalongkorn university and nuclear medicine society of Thailand. Hopefully, nuclear medicine in Thailand will have a bright progress strongly upon the well preparedness of manpower particularly young active nuclear medicine personnel, modern equipment and new technology in both imaging and radionuclide therapy as well as academic collaborations among international institutes.

	泰國		Achiraya Praisuwan	Professional Pharmacist, Lead GMP Inspector	Bureau of Drug Control, Thai FDA

摘要：

Bureau of Drug Control, Thai Food and Drug Administration (Thai FDA) is the national regulatory authority that regulates, evaluates and monitors the safety, efficacy, and quality of therapeutic and diagnostic products available to Thailand.

The regulations related to hospital radiopharmacy, industrial radiopharmacy, centralized radiopharmacy in Thailand were controlled by Bureau of Drug Control; Thai Food and Drug Administration, Ministry of Public Health and Office of Atoms for Peace, Thailand.

The regulations on licensing, import, market authorization, and post-marketing control system in Thailand. For the Radiopharmaceuticals, supervision in Thailand may be divided into two major categories:

- Radiopharmaceutical products which are intended to be used only in medical care for a specific patient (personalized) or clinical research. These products are exempted for the marketing authorization by hospital and clinical research exemption: Drug Act B.E. 2510 Section 13 (2) “production of drugs in accordance with the prescription of a practitioners of medicine or practitioners of the healing arts for a particular patient” and “importation by ministries, sub-ministries and departments which have a duty to prevent or treat disease”.
- Radiopharmaceutical products which are intended for commercial use. According to the Drug Act B.E. 2510, Section 12 “To produce or sell a modern drug or import or order a modern drug into the Kingdom, unless he or she has obtained a license from the licensing authority. The application for and grant of a license shall be in accordance with the rules, procedures, and conditions prescribed in the Ministerial Regulation”.

These products should be complied with related regulations as importation, licensing, marketing authorization, and post-marketing control (GMP compliance verification, Pharmacovigilance).

	Bureau of Drug Control, Thai FDA will be regulating the radiopharmaceuticals approval process under the Drugs Act, related regulations, and guidance. Before a medicinal product can be distributed and sold in Thailand, the corresponding manufacturer must have a GMP compliance status. For GMP regulation, Thai FDA, as part of PIC/S participating authorities, conduct the GMP inspection for manufacturers following the current version of PIC/S Guideline. Moreover, the import of medicinal products should be submitting the documents to verify the GMP compliance status as per the Thai FDA Notification on GMP Clearance of Overseas Pharmaceutical Manufacturers B.E. 2560.

下午 第 1 場	越南		Professor Mai Trong Khoa	Formal President	Vietnamese Radiology and Nuclear Medicine Society

摘要：

Nowadays, in Vietnam, Nuclear Medicine has been utilized to diagnose and treat cancer and some other diseases.

The whole country has 25 SPECT, 15 SPECT / CT, 12 PET / CT, for the diagnostic. Currently, Vietnam has applied many radioactive isotopes and radioactive pharmaceuticals for treatment, such as I-131, P-32, Y-90, I-125 (radioactive seed implant), ... in the treatment of cancer, differentiated thyroid cancer, hyperthyroidism, simple thyroid goiter, bone metastatic cancer, primary and secondary liver cancer, prostate cancer…. The permanent radioactive seed implant with ^{125}I in treatment of prostate cancer and the Selective internal radiation therapy system (SIRT) with Y-90 for the treatment of hepatocellular carcinoma and liver metastatic cancer have been successfully applied for the first time in Vietnam with high treatment efficiency and safety while improving the quality of life for patients.

For the first time in Vietnam, PET/CT has been used to simulate radiation therapy planning for cancer patients with 3D radiotherapy, IMRT,... Targeted therapy by RadioImmunoTherapy (RIT), with Rituximab monoclonal antibodies attached to radioactive isotope ^{131}I, has been used to treat lymphoma patients.

All nuclear medicine facilities in the country have applied the majority of radioactive isotopes and routinely marked compounds in the world for the diagnosis and treatment of diseases. This source of Radiopharmaceutical is partly produced at Da Lat Nuclear Reactor, the rest must be imported from abroad. The whole country currently has 12 PET/CT units and 5 cyclotrons including 3 active cyclotrons and 2 cyclotrons without an active license. There are a lot of new radiopharmaceuticals, marked compounds for diagnosis and treatment.

	越南		Nguyen Dieu Ha	Deputy Director	Pharmaceutical Business Management Division,DAV

摘要：

Radiopharmaceutical (Radioactive Drug): Drug that contains radionuclides used for diagnosis, treatment of diseases in humans or medical-biological research, including:

Radioactive isotopes or Radioactive isotopes combined with tracers.

I. CONDITIONS FOR TRADING IN RADIOPHARMACEUTICAL (Article 34 Law on Pharmacy)

1. Any establishment trading in radiopharmaceuticals must be approved in writing by a pharmacy authority (Certificate of Satisfaction of Conditions for trading in pharmaceuticals).
2. Establishment trading in radiopharmaceuticals must fulfil:

A. Every condition specified in Article 33 of Pharmacy Law corresponding to the conditions for each type of establishment:

- Material/ technical facilities and personnel resources;
- Pharmacy practice certificates of the person in charge of pharmacy expertise and the persons holding the specified positions

B. Security Measures (Articles 43- 48): Material/ technical facilities; Personnel resources; Mechanisms for Drug Delivery, Transportation, Buying and Selling, Report, Disposal 3. Satisfy the conditions specified in the Law on Atomic Energy and relevant legislative documents.

II. Radiopharmaceuticals may only be used for people when Marketing approval (Drug Registration No.) is granted

1. Drug Import license is granted (if no Drug Registration No. granted yet)
2. Public health establishments: buying radio-pharmaceuticals in the form of Drug Bidding

III. Proposals and Recommendations

The management of radiopharmaceuticals should be strengthened to ensure drug quality, safe and rational use for patients instead of just managing radiation safety as before.

1. It is necessary to coordinate and unify between the state management over healthcare and the state management over radiation safety, in order to facilitate businesses and drug using establishments to avoid overlapping regulations that waste time and resources of enterprises
2. Proposal: amending and supplementing Laws and relevant legal documents to unify the management between the Ministry of Health and the Ministry of Science & Technology.
3. Strengthening quality control for both locally produced radiopharmaceuticals and imported radiopharmaceuticals.
4. Enhancing information exchange and training between state management agencies on health and state management agencies on radiation safety.
5. Need support from International Atomic Energy Agency (IAEA) and regulators of radiopharmaceuticals of countries in the world, particularly countries in our region.

下午 第 2 場	緬甸		Professor Kyin Myint	President	Myanmar Society of Nuclear Medicine

摘要：

Background: The Department of Radioisotope, the forerunner of future Department of Nuclear Medicine was founded at Yangon General Hospital in 1963, following the visit of Dr. E. H. Belcher, the then Head of the Division of Life Sciences of the International Atomic Energy Agency (IAEA), and consultation with local health authorities (Ministry of Health, Myanmar). Continuous development of Rectilinear scanner (1966), Three-probe scintillation detector (1968), Planar Gamma Camera and RIA automatic well-counter (1974), SPECT gamma camera (2000), SPECT-CT (2014), PET-CT and 18 MeV CYCLOTRON (2015) provide effective clinical uses of Radio-isotopes for the people of Myanmar, improving health-care status. Radioiodine (131I) therapy for thyrotoxicosis and Differentiated Thyroid Carcinoma has been done since 1974. Postgraduate program of one-year Diploma course has started in 1997 and upgraded to three-year Master degree in 2007 in affiliation with University of Medicine 1, Yangon. Myanmar Nuclear Medicine Society (MNMS) was formed in 2014 and the present membership status is about 50. Departments of Nuclear Medicine in Myanmar are planning to introduce PRRT and Theranostics with existing hybrid imaging facilities (SPECT-CT & PET-CT).

Methodology: The Government of MYANMAR in collaboration with International Atomic Energy Agency (IAEA) has played a pivotal role not only for successful implementation of the projects, but also for sustainable growth and upgrading of Nuclear Medicine services in MYANMAR.

Conclusion: Myanmar Nuclear Medicine society is a major steering body to communicate with other allied societies for the upgrading and sustainable growth of Nuclear Medicine services in Myanmar.

	緬甸		Mr. Thet Zay Yar Myint	CEO	Lucky Charm Co, Ltd. SINGAPORE

摘要：

Background: Republic of the Union of Myanmar, mainland of about 50 million populations, , and radiopharmaceuticals need to be imported from abroad via the Myanmar citi has 4 public and 3 private Nuclear Medicine departments. All the Nuclear Medicine Instrumentations, Radioisotopes zen's company. There are three local companies running for the Nuclear medicine infrastructure of Gamma Camera, SPECT-CT, PET-CT and Cyclotron (such as, SIEMENS, GE, Philips, and IBA). But, there was only one local company running supply of radio-isotopes and radiopharmaceuticals for many years. All the consumables were imported from ANSTO, Australia with many limitations.

Methodology: Knowing the limitations and problems encountered in the country, we find out other possible alternatives. We achieved the import licenses from Department of Atomic Energy (DAE) and Ministry of Trade with the support of local consumers and confidence from the radiopharmaceuticals companies in abroad (Mostly from the west). Food & Drug Authority (FDA) under the Ministry of Health & Sports is finding out the way to handle radiopharmaceuticals, but not approved yet.

Results: We become the sole distributor of radio-isotopes and radiopharmaceuticals in Myanmar, because of cost-effectiveness. We have already run the business for three years.

Conclusion: Nuclear Medicine services are booming up among the clinicians in the management of cancer and other non-communicable diseases (NCD). FDA of Myanmar is finding out the best way for regulation of radiopharmaceuticals, regarding effective use of radio-isotopes and radiopharmaceuticals in the health-care system of Myanmar.

五、 會議議程

2019 Taiwan-ASEAN Nuclear Medicine Forum

Date:July 26, 2019

Venue: Ho Ying Tsai Memorial Hall, Shou-Ren Building, in NYMU

Time	Subject	Speaker
09:00-09:20	Welcome remarks	Prof. Jaw-Jou Kang, Dean, School of Pharmaceutical Sciences, NYMU.
	Addresses by Honorable Guests	Dr. Hei-Kuang Lee Ph.D, Deputy Director-General INER. Prof. Muh-Hwa Yang, Vice President, NYMU.
	Group Photo	All
Moderator Dr. Chih-Hsien Chang, Ph.D, Director, Sec. Isotopes Application INER		
09:20-09:50	Use of Nuclear Medicine in Taiwan	Prof. Ruoh- Fang Yen, M.D., President, Taiwan Society of Nuclear Medicine
09:50-10:20	Regulation of Nuclear Medicine in Taiwan	Ms. Mei-Chen Huang, Section Chief,Division of Medicinal Products, Taiwan FDA.
10:20-10:40	Coffee Break	
Moderator Prof., Pan-Fu Kao, M.D., President, Taiwanese Society of Medical Cyclotron		
10:40-11:20	Use of Nuclear Medicine in Thailand	Prof., Yuthana Saengsuda, President, Nuclear Medicine Society Thailand
11:20-12:00	Overview of Regulatory Framework of Radiopharmaceuticals in Thailand	Ms. Achiraya Praisuwan, Professional Pharmacist, Lead GMP Inspector, Bureau of Drug Control, Thai. FDA.
12:00-13:00	Lunch	

		Moderator Prof. Wen-Sheng Huang, M.D., Director, Dept. Nucl Med TVGH.
13:00-13:40	Applicaion of Nuclear medicine in the diagosis and treatment of cancer in Vietnam	Prof., Mai Trong Khoa, Vientamese Society of Radiology and Nuclear Medicine
13:40-14:20	Regulation of Radiopharmaceutical in Vietnam	Ms. Nguyen Dieu Ha, Deputy Director of Pharmaceutical Business Management Division, DAV.
14:20-14:40	Coffee Break	
		Moderator Prof., Jaw-Jou Kang, Dean, School of Pharmaceutical Sciences, NYMU.
14:40-15:20	A long Journey of Nuclear Medicine in Myanmar	Prof., Kyin Myint, President, Myanmar Nuclear Medicine Society
15:20-16:00	Experience of Nuclear Medicine Logistics in Myanmar	Mr. Thet Zay Yar Myint, CEO, Lucky Charm Co, Ltd. Singapore

六、 活動紀錄


2019 Taiwan-ASEAN
Nuclear Medicine Forum


2019 Taiwan-ASEAN
Nuclear Medicine Forum


2019 Taiwan-ASEAN
Nuclear Medicine Forum
Dr. Hei-Kuang Lee Ph.D

（一） Use of Nuclear Medicine in Taiwan

講者：中華民國核醫學學會 顏若芳 理事長

核醫造影技術目前已廣泛地應用於臨床診斷及新藥研發上，不論在腦神經造影、腫瘤造影及心血管造影等領域中，皆扮演著舉足輕重的角色。根據聯合國原子輻射效應科學委員會（United Nations Scientific Committee on the Effects of Atomic Radiation, UNSCEAR）估計，醫療輻射是人造輻射的主要來源，全球每年約有 36 億次的醫療輻射診療過程，包括放射診斷、核子醫學與放射治療等，貢獻超過 90%的人造輻射劑量且逐年增加中。核子醫學在臺灣雖然僅貢獻醫療輻射總有效劑量的 13.6%，但核醫在生理及功能的診斷方面確實具有不可取代的地位，尤其是近年來分子影像的興起，更為核子醫學開啟了嶄新的一頁。

目前臺灣核醫現況為 Cyclotron 機器 13 台、PET/CT 有 50 台以上，且擁有 113 台以上的 SPECT 機器；而臺灣核醫會主要由 500 位以上核醫醫師、放射師、醫檢師、藥師及核醫學會會員所組成。

臺灣於 2000-2012 年之間統計發現平均每年核醫診療健保使用量為 251,000 次，約為每千人 10.9 次，核醫總使用量隨時間增加。

其中以全身骨骼掃描是最常進行的檢查項目，平均每年每千人 4.05 次，佔所有核醫診療的 37%。而核醫使用於研究方面的統計可以發現，主要以全身骨頭掃描 (37%)為主，其次為心肌灌注掃描 (Myocardial perfusion scan) 及全身 PET 掃描 (27.4%)。

由於心導管手術數量近年來顯著上升，而心肌灌注顯像(MPI)可發揮心導管手術守門員的角色。與初始侵襲性冠狀動脈移植造影(CAG)相比，在疑似心臟冠狀動脈疾病 (CAD) 的的患者中，心肌灌注顯象引導的選擇性策略與較低的血運重建和心肌梗死發生率相關，並提高了生存率。

臺灣健保自 2016 年起開始給付 FDG PET，主要針對癲癇病人手術計劃的焦點檢測、心衰竭中活體心肌手術以及 9 種癌症，其中包含乳癌、淋巴癌、結腸癌、食道癌、頭頸癌、肺癌、黑色素瘤、甲狀腺癌以及子宮頸癌。而正子癌症應可用於癌症分期、治療監測、復發監測以及分期鑑定，當 CT / MRI 結果不確定時，須在圖中說明其必要性，並積極作進一步治療。

臺灣核醫健保支出有逐年成長，但整體費用仍低於總支出 0.5% 以下，可能與各類檢查給付較低有關。支出成長部分，除檢查量提升外，可能與 Tc-99m 全球缺貨而導致取得成本大幅增加有關。核醫檢查藥物所使用之放射性同位素以反應爐生產佔多數，尤其是以 Tc-99m 標定的藥物佔了七成以上，自 2010 年起，健保署為因應 Tc-99m 全球缺貨而導致取得成本大幅增加，針對全身骨骼掃描項目開放醫院得多申報 750 點，惟對於其餘亦使用 Tc-99m 標定的藥物，並無開放此項作法。台灣的 Tc-99m 藥物主要倚賴進口 Mo-99/Tc-99m 孳生器製作，孳生器的原料 Mo-99 目前則由九個國家的醫用反應爐供應。

臺灣可取的正子造影藥劑當中，健保給付 I-131 可用於甲狀腺癌且 Ra-223 可用於前列腺癌骨轉；Y-90 Microsphere 藥劑可用於肝癌轉移病人，雖然有食藥署藥證，但健保並未給付；I-131 MIBG 藥劑可用於嗜鉻細胞瘤，神經母細胞瘤，至今仍無食藥署藥證，若需供人體試驗，則須以專案進口或製造。

自 1995 年以來，NIH 報銷並沒有調整，但是放射性藥物和掃描

儀的價格已大幅上漲，且核醫學研究使用不足，尤其是 PET 掃描。大部分醫生們不願意使用 PET 掃描，因為擔心 NHI 會減少費用，對 TFDA 的監管，一些現有藥物的許可證已被暫停，而新藥物由於漫長而繁瑣的過程而無法進入，但核醫藥物不應與普通藥物相同。

（二） Regulation of Nuclear Medicine in Taiwan

講者：食品藥物管理署藥品組 黃玫甄 科長

放射性藥物其定義為含有放射性物質供人類使用的藥物。在對人類施用後，該藥物可以診斷、監測、治療，甚至是緩解疾病狀況或實現其他醫療效果，其組成包含放射性核種及非放射性藥物，主要用於診斷與治療。

根據藥品註冊管理條例第 43 條，放射性藥物註冊應與放射性藥物之藥物申請一併提交。且申請應符合中央衛生主管部門公佈的「核醫放射性藥品臨床試驗基準」和「核醫放射性藥品審查基準」。本章規定的新藥規定也適用於新劑量的放射性藥物。註冊放射性藥物所需文件包含藥物描述、規格、非臨床動物研究報告、臨床試驗報告及輻射劑量研究報告，有關各種應用的詳細要求，參閱放射性藥物註冊

為新藥所需的技術文件中附錄 11 的清單。

目前臺灣 TFDA 核准使用的放射性藥物共有 56 件，其中有 64%須從國外進口，36%由臺灣自行生產；而放射性藥物當中，88%主要為診斷疾病使用，另外 12%為疾病治療使用。臺灣至今有 9 家醫院提供正電子發射斷層掃描 (PET) 檢測以及 1 家生產 PET 藥物之藥廠，依「斷層掃描正子放射同位素調製作業要點」使用放射性同位素(PET 藥物) ，病人接受診斷與治療的所有過程皆由 TFDA 監控。「斷層掃描正子放射同位素調製作業要點」主要參考美國 FDA PET Drugs-CGMP，目的為了確保正子放射性同位素的安全性及品質，並且僅適用於半衰期短的放射性同位素 (e.g. F-18、C-11、N-13 等)。這些正子放射性同位素處方可以在正子中心調製，但僅能經由專業培訓的操作員和藥師操作。

臺灣 TFDA 未來針對於核醫藥，需要不斷修訂並更新監管要求，使其更符合國際標準，主要包含核醫放射性藥品審查基準、核醫放射性藥品臨床試驗基準、斷層掃描正子放射同位素調製作業要點以及促進放射性藥物的開發。

（三） Use of Nuclear Medicine in Thailand

講者：泰國核醫學學會 Yuthana Saengsuda 理事長

泰國至今核醫學會共有 375 位會員，其中有 95 位核醫醫師，其餘皆為技術員、放射師、藥師及護理師。而泰國共有 29 個核子醫學中心，其中 22 座為公家醫院，另外 7 家為私立醫院。泰國共有 4 座 Cyclotrons，3 座位於曼谷，1 座位於泰國北部的清邁大學醫院。

泰國約有 6900 萬人，並僅有 11 台 PET/CT 儀器，其使用狀況為 1 台 PET/CT 儀器要負荷 627 萬人。相較於韓國，由於韓國本身有 148 台 PET/CT 儀器，而 1 台儀器僅需負荷 32 萬人。

泰國報銷 PET / CT 研究費用僅適用於政府官員部門，由於政府預算有限，因此僅有 2 種適應症可被批准使用 PET/CT，包含非小細胞肺癌以及疑似復發性結腸癌。泰國核子醫學會仍不斷申請其他病症其 PET/CT 使用，但仍未獲批准。2016 年，泰國共有 59455 件核子醫學研究計畫，主要包含骨掃描、全身掃描、心臟掃描、PET 腫瘤掃描以及甲狀腺掃描。

泰國有一家運營放射性藥物公司將醫院、診所和醫療成像中心的患者使用之特定藥劑調製、分配和分發。這些個體化處方主要用於正子成像以利檢測、診斷和治療腫瘤、心臟病，神經疾病等。泰國有兩家公司供應 Tc-99m 單位劑量，而這些核醫藥技術研究所主要為私人公司，依其單位劑量和價格標準不同，彼此互相競爭。

Wattanosoth 是泰國最大的私立醫院，並擁有 PET / CT 和 Cyclotron。Chulabhorn 是政府部門，亦是國家 Cyclotron 和 PET / CT 中心，所以 Wattanosoth 和 Chulabhorn 皆能供應 PET 追蹤劑 F-18 FDG，以價格低廉價格來互相競爭。自 2017 年 12 月開始，Chulabhorn 可以提供 Ga 68-dotatate 和 PSMA 用於臨床成像。

泰國提供 PET 追蹤劑的劑量增加 30%，主要是 F-18 FDG。因此，泰國的 PET 研究數量正在增長。將來， O-15-water PET 定量心肌灌注的 PET 研究可用於個體化與標準化的血管區域監測。

自 2018 年開始使用 PSMA 配體和 PRRT 肽受體放射性核素治療，並將推出 Ac-225 dotatate 目標 alpha Px，主要因為其優於 β 發射之 $^{177}LuCl_3$，在文獻的初始結果中較安全和較少的副作用。2018 年第一次 Lu-177 PSMA 120 mCi 的注射，結果顯示 5-10%的 PC 不表達 PSMA，主要因為其缺乏 PSMA 攝取阻礙，且注射後病患應充分補充水份以利腎臟排泄，4 小時護士的輻射劑量為 6-4 microSv，但其可能有腎臟，唾液腺，淚腺之器官毒性。

（四） Overview of Regulatory Framework of Radiopharmaceuticals in Thailand

講者：泰國食藥署藥物管制局 Achiraya Praisuwan 領導 GMP

泰國核醫藥生產在法規上需要經過二大單位核可，一為原子能和平辦公室 (OAP) ，一為泰國 FDA。關於原子和平辦公室負責的事項為申請使用放射性物質許可證，泰國 FDA 則會監控核醫藥申請所有文件，包含臨床前期及臨床試驗結果、營銷許可證、新藥申請文件

以及新藥生產文件。泰國 FDA 的使命在於監督、供應、組織和管理所有核醫藥，管理項目包含生產、進口、運輸和儲存、分發以及提供藥物的準則。

泰國核醫藥的管理可分成二大類，一為醫療照護以及臨床研究，另一為商業化。醫療照護以及臨床研究層面而言，醫療從業者或治療藝術從業者的處方主要為特定患者調劑藥物，並有責任預防或治療疾病。法規層面而言，泰國 FDA 需通報海外藥品製造商符合 GMP 法規，並對藥物警戒和產品安全進行監測。

生產放射性藥物監管程序如下，首先需要申請生產放射性藥物的許可證，並對放射性藥物的產品進行註冊申請，接著提交 CTD，最後得到合格的註冊證書，且效期維持 7 年。另外，GMP 認證其證書效期為 3 年，並以風險為基礎的方式重新檢查其生產過程。

進口放射性藥物的註冊程序需要 OAP 許可，進而填寫藥物進口申請表，連同放射藥物產品註冊申請表一同繳交給 CTD。除此之外，GMP 合規性查驗需要提出藥品證書 CPP 或 GMP 證書。

泰國針對於放射藥物的安全性、品質以及 GMP 認證的指導文件仍在修改當中尚未公告，故現階段的放射藥物只須符合 GMP 規範以及 PIC/S 指南。除此之外，根據國際藥典的規範，泰國將來會依照世界衛生組織聯合控管放射藥物的品質以及安全性為依歸，並制定關於放射性藥物產品特定註冊的指南以及制定醫療機構藥品製劑良好實踐指南。

（五） Application of Nuclear medicine in the diagnosis and treatment of cancer in Vietnam

講者：越南核醫學學會 Mai Trong Khoa 副理事長

目前越南僅有一座核藥反應爐，若要供應全越南的核醫藥研發，較為困難。越南雖然有 5 座 Cyclotron，但實際上僅有 2 座目前仍有在運作。

根據 2018 年國際癌症研究中心 IARC 統計結果顯示，越南罹患癌症的族群高達 9400 萬人口，每年有 165,000 名癌症新例且每年有 115,000 人因癌症死亡。

越南的核醫學主要應用在於腫瘤學，心臟病學，神經學及內分泌學等，其中 90%以上應在在於腫瘤學，神經學以及內分泌學相對較少。放射醫學在越南的應用包含放射學、核醫學和放射腫瘤學，而有許多新的輻射技術可用於疾病的診斷和治療，特別是在腫瘤學領域。由於越南癌症發病率和死亡率逐年攀升，為了滿足患者的診斷和治療需求，放射科、核醫學及腫瘤科中心之數量可能會相對增加。

越南放射治療計劃中的 CT 輻射量模擬包含 CT、GTV、CTV 及 PTV；而 PET / CT 模擬包含 BTV，可應用在監測腫瘤體積及腫瘤代謝，以利於早期診斷和治療。有一位個案，年齡 59 歲，患有肺腺癌第一期，長期乾咳，治療前腫瘤體積為 2 ~ 3 公分，標準攝取值為 6.89，經過三次化療之後，標準攝取值降至 3.24；經過六次化療和放療之後，病患不再咳嗽，身體復原狀況佳，雖有一些輻射併發症，但病患因預後狀況佳而享有良好的生活品質。

關於前列腺癌的治療可採用永久性放射性 I-125 種子植入物，I-

125 種子直接植入前列腺腫瘤以破壞腫瘤，較不會影響周圍健康器官，如膀胱，直腸等，以減少患者的併發症，因此基本生理功能仍然存在。永久性放射性 I-125 種子植入物自 2015 年 4 月起首次在巴赫邁醫院 (Bach Mai hospital)的核醫學和腫瘤中心進行，至今已有 10 名以上病患已接受前列腺癌治療，且 100%有症狀減輕的情形，PSA 值也回復正常指標，生活品質也獲得改善，並無嚴重的併發症產生。有一 63 歲男性個案，是越南第一位接受永久性放射性 I-125 種子植入治療的前列腺癌患者，治療前病患主要病狀有頻尿以及尿滯留，PSA 值為 28.5ng / ml，MRI 影像顯示前列腺腫瘤微創精囊，治療後，病患可以正常的小便，PSA 值降為 0.91ng / ml，MRI 影像發現前列腺腫瘤已消失。

原發性和繼發性肝癌治療可採用選擇性內部放射治療 (SIRT) 與 Y-90 微球，將放射性 Y-90 微球置於肝腫瘤動脈中，微球會使供血動脈栓塞並透過 Y-90 的 β 能量破壞腫瘤細胞，目前已有 57 例患者治療效果良好，效率高，安全性高。

在越南 BACH MAI 醫院放射外科採用旋轉 GAMMA 刀治療 6000 名腦腫瘤和顱內疾病患者，手術前腫瘤平均大小為 2.9±1.5cm，手術後約在 6 個月後穩定控制預後，並在 6 年後，腫瘤大小減少至 0.4±0.7cm。

未來進一步的輻射技術在越南的應用包含混合成像的追蹤器以及用於 PET 的新型放射藥物 (e.g. Na-^{18}F、^{18}F-FDG、^{11}C-Choline、^{68}Ga-NeoBOMB1 及 ^{68}Ga-PSMA)。另外，胜肽受體放射性核素治療 (PRRT) 也是將來應用的放射性治療之一，主要使用與胜肽結合的放射性同位素的方法，該複合物通過腫瘤細胞表面的胜肽受體進入腫瘤細胞並破壞它。

（六） Regulation of Radiopharmaceutical in Vietnam

講者：越南 DAV 製藥業務管理組 Nguyen Dieu Ha 副組長

越南主要監管之放射性藥物包括放射性同位素或以及放射性同位素與追蹤劑。根據放射性藥物交易的條例第 34 條，任何有關放射性藥物交易之企業必須取得藥房管理局書面批准並符合政府規定。

放射性藥物製造商其材料與生產設備應為 GMP 製造工廠，並具有進行輻射工作的許可證，且儲存放射性藥物的獨立倉庫需符合 GSP 要求的分離區域。根據衛生部法規，記錄和管理檔案和書籍的系統需備查。其中放射性藥物廠負責人須具有藥學中級學位、放射化學學士、放射醫學或核醫學專業學士，主要工作內容為監督研究，生產、分析和測試過程。

針對於放射性藥物進口商、出口商和批發商其倉庫須為合規之 GSP/GDP 倉庫，根據衛生部法規，管理檔案及書籍系統需符合原子能及核能之規定。衛生部授予具有藥品進出口功能的企業許可證有效期為 1 年，科學技術部輻射安全司主要管理放射性藥物進口、生產及運輸許可證；此外，根據越南「原子能法」之規定，放射性醫療

檢查及治療設施之許可證有效期為 1 年。用於人體的放射性藥物需具有批准營銷許可證、藥品進口許可證。

將來，越南藥房管理局希望強對放射性藥物的管理，以確保藥品品質以及對患者之安全性考量。不僅加強對當地生產的放射性藥物和進口放射性藥物的品質控制，並加強國家管理機構之間對於輻射安全的衛生和國家管理機構之間的信息交流和培訓。此外，希望能獲得國際原子能機構 (IAEA) 和世界各國放射性藥物監管機構的支持。

（七） A long Journey of Nuclear Medicine in Myanmar

講者：緬甸核醫學學會 Kyin Myint 理事長

緬甸僅有 4 間醫院有提供核醫學服務，包含 Yangon General Hospital、North Okkalapa General Hospital 、Mandalay General Hospital 及 Naypyitaw General Hospital。

緬甸核醫學研究可分為 SPECT-CT、體外研究、PET-CT 及放射性碘，其中 SPECT-CT 用於一般核醫學成像，如甲狀腺掃描，骨掃描，腎臟掃描，心肌灌注成像，肝臟掃描，肝膽成像，甲狀旁腺掃描

等；體外研究主要針對甲狀腺相關激素進行放射免疫測定；PET-CT 主要應用於腫瘤學 (^{18}F-FDG)；放射性碘(^{131}I 溶液) 用以治療甲狀腺毒症和分化型甲狀腺癌。

緬甸身為一個開發中國家，但並無完善健康保險制度，因此若要以放射性治療輔助人類疾病的診斷和監控，政府支持便能發揮關鍵作用，但由於預算有限，很多進程受到限制。然而，我們的目標希望緬甸核醫學服務能符合國際公認標準並提供更廣泛之核醫學服務，並成為卓越核醫學中心。

（八） Experience of Nuclear Medicine Logistics in Myanmar

講者：新加坡 Lucky Charm 公司 Thet Zay Yar Myint 執行長

Radiance Infinity 公司於 2012 年成為緬甸放射性藥物供應商之一，由於資源有限且患者人數逐年增加。因此 Radiance Infinity 開始進入放射性藥物市場。Radiance Infinity 一直致力於為緬甸公家醫院和私人專科診所提供高品質的放射性藥物，並用於診斷和治療。Radiance Infinity 的核心價值為誠信、活力、卓越和以及提供安全的放射藥物。

每位員工以誠信和奉獻精神為大家公同信念，並共同完成日常業務以達成目標。

核子科學業務包含核醫學 PET / SPECT、放射治療和診斷成像並提供 Hotlab 成立和放射性藥物解決方案，並提供工業和研究市場的各種輻射防護和分析設備。Radiance Infinity 業務範圍包含研發製造核醫藥、國土安全維護、衛生保健及製藥研究。緬甸所有放射性物質和輻射裝置的進口、分配、擁有為 DAE (原子能部) 控管，且 DAE 為控制放射性物質出口的唯一機構。緬甸 FDA 目前不涉及放射性物質的控制 (包 Tc 發生器和 Iodine-131)。但 DAE 正在使用 IAEA 法規作為指導和參考，希望能滿足緬甸的需求。

Radiance Infinity 供應的產品包含生物放射性安全櫃、PET 單位劑量櫃、劑量校準器、熱實驗室設置及鉛屏蔽廢物容器。

（九） 討論

Q1: 今天早上有提到 Lu-177 DOTATATE 的臨床試驗，受人體試驗委員會核可後，就不需再經 FDA 的審核，在試驗過程中還需要向 FDA

定期報告，還是只需向醫院主管機關報告？
A1:
(1)以泰國來說，當試驗需在醫院進行，像是 Lu 或是 Ga DOTATATE 相關的試驗，我們在朱拉隆功醫院裡的藥師會負責監督，所有試驗的紀錄都是可被運用的，也可以當作病人使用的參考依據。FDA 則訂有相關法律。
(2)大學或醫院當中都有人體試驗委員會確保試驗的安全性，核藥在處方及藥物使用上是具備豁免權的，而其他藥物則需受到泰國 IND 的管理。

Q2:研究過程中醫院 IRB 負責整個試驗責任，不用寄送相關記錄到 FDA?
A2:目前法規訂定有些事不明確的，還有很多部分是需要再改進的，但安全性、療效性是我們想更進步的。

Q3: 核藥與其他藥物是很不一樣的，有所限制的情形下，仍須有好的診斷與治療，此時也需搭配更好的法規來輔助進行，我們也應遵守並實行。而核藥的架儲期也短，如果有好的規範就更能妥善運用在病人身上。
A3: 我們能在醫院中使用核藥，並嘗試用在更多的疾病治療。
在緬甸，核藥的管理不是在 FDA 底下，而是在其他部門進行管理，因此使用上的狀況是更加複雜的，這也是我們所面對的問題。

Q4: 想問核藥費用支出的方式是如何進行的？
A4: 由我們國民健康保險負擔，而我們是用包裹式的方法給付，只給 FDG，如果有其他想做的項目，則需自行負擔部分費用。檢驗的部分是同個包裹底下的，但治療的費用會另外計算。
有些比較昂貴的檢測，像是心肌梗塞的影像呈現、PET scan，我們有些審核的程序，其中會邀請專家評估這些檢測項目是否應實行，如果不符合的話，就無法得到健保給付。醫生也會因此審慎評估是否需要

提供病人相關的檢測。
在越南，核藥相關的診斷和治療費用完全由政府支出。但核藥需要有藥證，政府也會返款 40%，因為在 microfield 的研發成本相對是更昂貴的，而病人需支付 60%
泰國政府通常也會負擔核藥相關費用，如果是官員等等的病人到醫院去也能獲得相關給付。如果今天有一個社會工作者，領有社會保險，他需要到醫院註冊，而有些特殊技術仍是要自費的。

Q5: 想請問在泰國，「鎦」的使用還在臨床試驗階段，還是已經進入實際治療的部分了？
A5: 現在可以用了，根據泰國的 FDA 核可，但病人需要自己支付相關費用。
（補充）台灣的部分，病人在用到藥物之前，藥物要先經過官方核可才能使用，也包含核藥的部分，因此經由臨床試驗，再領取核可證，仍是必經之程序。試驗過程中是不能像病人收錢的。

Q6: 不同地方不同法規的臨床試驗，可以看到很多研究，在安全性的部分已經建立了很詳盡的資料和研究，我們可能可以和 TFDA、CDE 合作，利用現有的資料減少一些 safety studies 的部分，這非常重要。Safety 基本上是沒有問題的，但當我們重複了這些 studies，可能需要消耗更多的資源，而這也是我們需要更進一步和 TFDA 進行討論的。
A6: 立法單位和民眾對於這部分是有疑慮的，這也是為何我們仍強調需要進行安全性試驗的部分，就算是臨床試驗也需要進行。CDE 的執行長說會再跟對這些問題進行討論，雖然廠商都希望可以加速審核的過程，但有太多臨床前試驗是需要被審核的。
在泰國，我們也在等待泰國 FDA 建立更完善的法律，舉例來說 PET CT scan 目前只有兩種適應症（肺癌及大腸癌）是可以給付的，而對象也僅限政府官員、軍人等等，在這之前病人要先完成 MRI、CT scan，如果看不到病灶的話要再加作 PET scan。在 lymphoma 也有 evidence base 的資料，利用 Ga-67 進行評估，但要自行負擔費用。

在大陸，病人自行負擔費用，醫生也不願意有健保支出，香港也是 self-paid 的方式。

印尼：會進行小組會議方式，來評估並決定是否給付給使用者，如果不被核可的話，就會走 self-paid。

泰國：朱拉隆功醫院有 PET Tester

越南：有 PET, CT 以及五台 Cyclotron

台灣：有 GMS, 在台中的 PET center 供應 FDG, 目前因為 PICS/GMP 的規定而需禁止 cyclotron 能夠在院內販售 FDG 的狀況，反而只剩經核准的藥商可以販售，但此議題仍在討論當中。

七、 與會人員簽到單

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No.	Title	Name	Signed
1	Professional Pharmacist, Bureau of Drug Control, Thai FDA	Achiraya Praisuwan	
2	Deputy Director, Pharmaceutical Business Management Division,DAV	Nguyen Dieu Ha	
3	President, Nuclear Medicine Society of Thailand	Prof. Yuthana Saengsuda	
4	Division of nuclear medicine	Sureerat Saengsuda	
5	Leturer in Mahidol Chivers	Putthiporn Charoenphun	
6	Rradiologist	Thawi Yingsa-Nga	
7	Formal President of Vietnamese Radiology and Nuclear Medicine Society	Prof. Mai Trong Khoa	
8	President, Vietnam Association of Radiological Technologists	Prof. Loc Thai Van	
9	President, Myanmar Society of Nuclear Medicine	Prof. Kyin Myint	
10	CEO, Lucky Charm Co, Ltd. Singapore	Thet Zay Yar Myint	
11	Medical Physicist	Rini Shintawati	
12	Radiographer	Siti Masrochah	

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序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
1	陽明大學 藥物科學院院長	康照洲教授							
2	臺北榮民總醫院 核子醫學部部長	黃文盛教授							
3	核能研究所 副所長	李海光博士							
4	核能研究所 同位素應用組組長	張志賢博士							
5	核能研究所 同位素應用組副組長	廖美秀博士			✓	✓	✓	✓	
6	核能研究所 同位素應用組副研究員	江東權			✓	✓	✓		
7	核能研究所 同位素應用組副研究員	陳俊宏博士			✓	✓			
8	核能研究所 同位素應用組副工程師	江昭志							
9	核能研究所 同位素應用組技術員	王世宇							
10	核能研究所 同位素應用組副工程師	曾玉琴							
11	陽明大學 副校長	楊慕華教授							
12	食品藥物管理署 藥品組科長	黃玫甄							
13	醫藥品查驗中心 執行長	高純綉							
14	臺北榮民總醫院 核子醫學部	楊邦宏							
15	台灣大學附設醫院 核子醫學部部長	顏若芳教授							

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序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
16	陽明大學	王信二教授	王信二						
17	陽明大學		劉仁賢				✓		
18	陽明大學	葉依瑄	葉依瑄	葉依瑄					
19	陽明大學	江仲文	江仲文	江仲文					
20	陽明大學	王誼豪	王誼豪	王誼豪					
21	陽明大學	施汝元	施汝元	施汝元					
22	陽明大學	陳妍年	陳妍年	陳妍年					
23	陽明大學	李品嫻	李品嫻	李品嫻					
24	陽明大學	陳沛穎	陳沛穎	陳沛穎					
25	陽明大學	郭彧延	郭彧延	郭彧延					
26	陽明大學	林育瑄	林育瑄	林育瑄					
27	陽明大學	陳昀	陳昀	陳昀					
28	陽明大學	陳雅媛	陳雅媛	陳雅媛					
29	陽明大學	楊裕萌	楊裕萌	楊裕萌					
30	陽明大學	鄭力誠	鄭力誠	鄭力誠					

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序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
1	GMS Thailand	Mark Gallegos							
2	GMS Thailand	Natthawuth Nainanont							
3	GMS Thailand	Supakit Hluangjork							
4	PTSGI	Joshua Pan							
5	士宣生技(股)	吉彥婷				✓			
6	士宣生技(股)	吳惠玲				✓			
7	士宣生技(股)	黃敬倫						✓	
8	核能研究所	周光暉							
9	核能研究所	夏建忠							
10	無	林漢民							
11	臺灣新吉美碩(股)	林鴻							
12	臺灣新吉美碩(股)	Amy Yu							
13	臺灣新吉美碩(股)	張碧芳							
14	臺灣新吉美碩(股)	鐘令雁							
15	臺灣新吉美碩(股)	陶澤文							

序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
16	陽明大學	李易展	李易展	李易展					
17	陽明大學	曾幸瑜	曾幸瑜	曾幸瑜					
18	醫藥品查驗中心	焦玉中	焦玉中	焦玉中					
19	醫藥品查驗中心	何昆瑾	何昆瑾	何昆瑾					
20	健保藥局	廖志裕	廖志裕	廖志裕		✓			
21	陽明大學	李繼仁							
22	陽明大學	吳東信	吳東信						
23	陽明醫放系	陳傳霖	陳傳霖	陳傳霖					
24	新光醫院	陳遠光							
25	核醫部	郭諭燁	郭諭燁						
26	臺大創新藥物研究中心	忻凌偉	忻凌偉						
27	士宦生技	陳維志							
28	國泰	謝秉原	謝秉原						
29	禾信	黃玉儀	黃玉儀						
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序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
1	三軍總醫院	周大凱	周大凱					✓	
2	三軍總醫院	朱曉梅	朱曉梅					✓	
3	三軍總醫院	施冠彣	施冠彣					✓	
4	三軍總醫院	邱創新	邱創新				✓		
5	三軍總醫院	陳穎柔	陳穎柔					✓	
6	三軍總醫院	林立凡	林立凡				✓		
7	三軍總醫院	曾大維	曾大維					✓	
8	三軍總醫院正子中心	詹啟仁	詹啟仁						
9	台大新竹分院	蔡雅琴	蔡雅琴				✓		
10	台大醫院	林培堯	林培堯					✓	
11	台北慈濟醫院	楊宗翰	楊宗翰	楊宗翰			✓		
12	永和耕莘醫院	徐偉傑							
13	永和耕莘醫院	林修寧							
14	安泰醫院	陳啟雲	陳啟雲				✓		
15	成大醫院內科	林錫璋	林錫璋	林錫璋			✓		

13

序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
16	亞東核醫科	汪姍瑩							
17	為恭紀念醫院	楊正							
18	高雄榮民總醫院	彭南靖	彭南靖	彭南靖	✓				
19	國泰綜合醫院	蘇弘毅	王世楨	王世楨		✓			
20	國泰綜合醫院	王世楨	蘇弘毅	蘇弘毅					
21	國泰綜合醫	陳孟麟	陳孟麟	陳孟麟					
22	新光醫院核醫科	葉加祿	葉加祿	葉加祿			✓		
23	義大醫院核醫科	殷國維	殷國維	殷國維		✓			
24	臺北榮民總醫院	張智勇							
25	臺北榮民總醫院	陳苓仕							
26	臺北榮民總醫院	朱力行	朱力行	朱力行	粉	✓	✓		
27	臺北榮民總醫院	楊宛甄							
28	臺北榮民總醫院	張文議	張文議	張文議	✓	✓	✓		
29	臺北榮民總醫院	魏文祥							
30	臺北榮民總醫院	張庭瑀	張庭瑀	張庭瑀					

序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
31	臺北榮民總醫院	徐丞	徐丞	徐丞					
32	臺北榮民總醫院	朱育萱	朱育萱	朱育萱					
33	臺北榮民總醫院	馬佳琦	馬佳琦	馬佳琦					
34	臺北榮民總醫院	黃延城							
35	臺北榮民總醫院	吳元鍾	吳元鍾						
36	臺北榮民總醫院	謝幸容							
37	臺北榮民總醫院	陳世沛							
38	臺北榮民總醫院	黃玉晴	黃玉晴	黃玉晴					
39	臺北榮民總醫院	呂雅萱	呂雅萱	呂雅萱					
40	臺北榮民總醫院	李繼仁	李繼仁	李繼仁					
41	臺北榮民總醫院	林仲信	林仲信	林仲信					
42	臺北榮民總醫院	林若瑜	林若瑜	林若瑜					
43	臺北榮民總醫院	利達洋	利達洋	利達洋					
44	臺北榮民總醫院	王亞晴	王亞晴	王亞晴					
45	臺北榮民總醫院	陳至豪	陳至豪	陳至豪	✓			✓	

2019 Taiwan-ASEAN Nuclear Medicine Forum

序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
46	樹林仁愛醫院	黃鉉儕	黃鉉儕	黃鉉儕				✓	
47	樹林仁愛醫院	莊家豪	莊家豪	莊家豪				✓	
48	醫院	陳婧顏	陳婧顏	陳婧顏	✓				
49	醫院	房逸雲	房逸雲	房逸雲		✓			
50	雙和醫院	鄭茹云							
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序號	單位	姓名	簽到	簽退	公務人員	藥師	核能醫學	放射師	備註
61	恩典科技	陳維宏	陳維宏						
62	恩典科技	王義文	王義文						
63	永日達公司	胡政隆	胡政隆						
64	腦科學中心	王寶弘	王寶弘						
65	核醫部	張玲	張玲						
66	核醫部	李哲能	李哲能						
67	核醫部	洪宗勳	洪宗勳						
68	長榮	陳志成	陳志成						
69	國泰醫院	蘇以超	蘇以超	蘇以超					
70	腦科學中心	王意忠							
71									
72									
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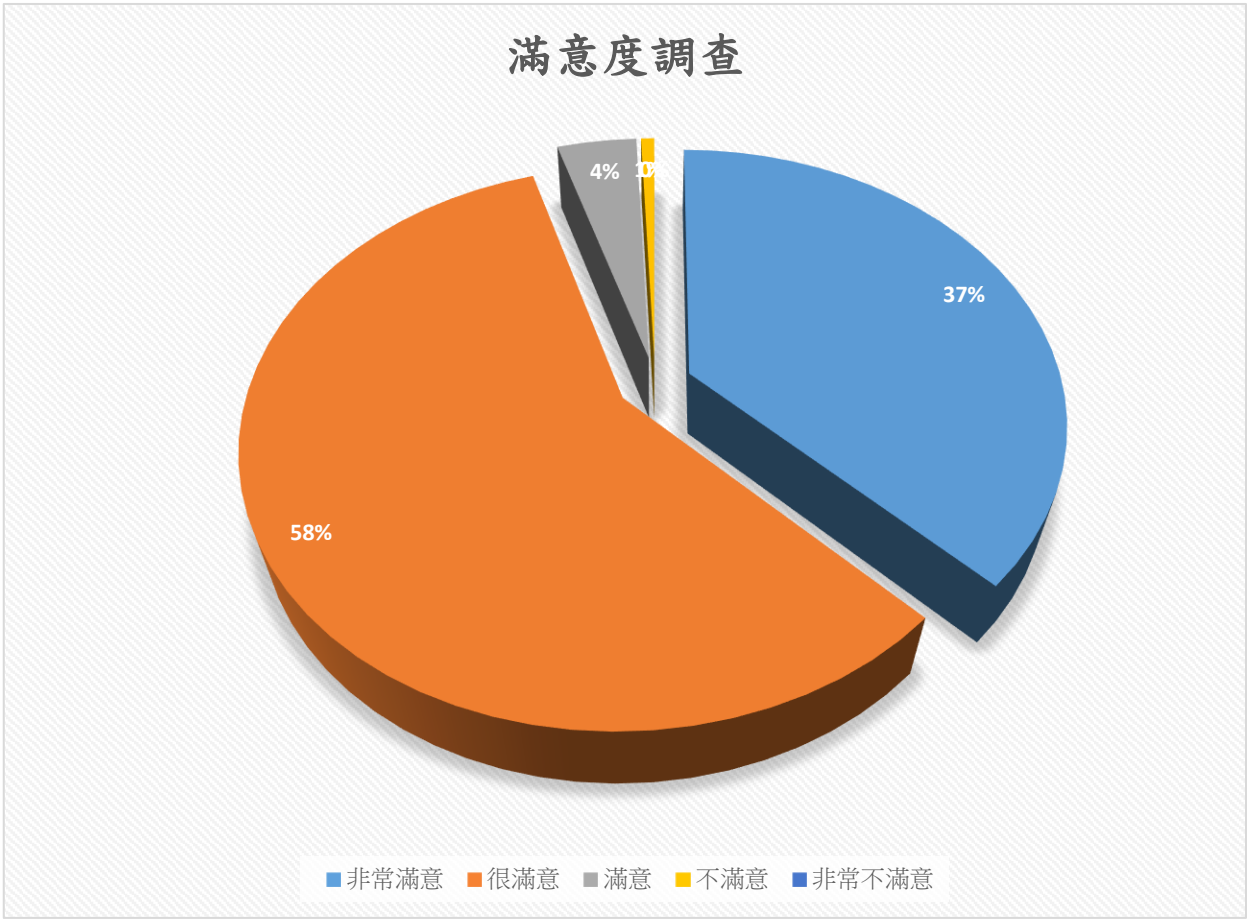
75									

八、 滿意度調查

本次會議有對參與者發出滿意度調查表，滿意度調查結果為非常滿意 37.4%、很滿意 57.8%、滿意 4.1%、不滿意 0.7%、非常不滿意 0%，來賓對於本次會議中討論各國核醫藥品的使用、發展狀況與法規部分皆表滿意，尤其對於最後部分討論提問部分表示非常滿意，唯一美中不足的覺得一個小時的討論時間太短。至於對本次會議不滿意的地方，是會場工作人員在會場中行動進而干擾到聽眾，關於這點是值得承辦單位改進部分，該如何在兼顧在不打擾聽眾前提下，並維持會議順利的進行的均衡點是值得承辦單位省思課題。



肆、 主要發現與結論

為深化以東協為核心之區域經濟整合，2011 年 11 月第 19 屆東協高峰會通過「東協 RCEP 架構文件」（ASEAN Framework for Regional Comprehensive Economic Partnership），並邀請與東協簽有 FTA 之 6 個對話夥伴(澳洲、中國大陸、印度、日本、韓國與紐西蘭)參與 RCEP。RCEP 由 16 個國家的組成，因各國管理法規、條件不一致，法規調和在整合中佔非常重要的角色。有鑒於此，東協於 1999 年成立 PPWG（Product Working Group on Pharmaceutical），積極處理東南亞醫藥法規協和方案，推行制定各國共同認可的藥品審查規範，讓藥品在東協內順暢流通。此外在藥品註冊統一格式方面，推行 ASEAN Common Technical Dossier（ACTD）的格式由於可以加速藥品在東協各國的申請。在不影響藥品的品質、效能和安全性的前提下，PPWG 負責制訂方案協和東協會員國之間的醫藥相關法規，以降低醫藥領域貿易上的技術障礙，促進藥品相關的註冊、貿易、合作等關係，以及完善和促成東協自由貿易區（AFTA）與東協經濟共同體（AEC）的目標。因此，由 PPWG 負責發展藥品法規協和計畫，來促成藥品的法規基準、要求與辭彙的協和。

本計畫為求我國核醫醫藥法規與東協核醫醫藥法規協和體系接

軌，為此除了蒐集泰國、越南與東協 PPWG 組織的相關法規加以研究外；利用主辦「“台灣 - 東協”核醫醫藥研討會」國際研討會的機會，邀請的東協各國官員參與，透過各國藥政管理體系之聯繫網絡，加強我國與各國的聯繫，並與各國交流學習及再教育的方式，加強並分享我國核醫醫藥管理的經驗，爭取參與國際核醫醫藥法規調和管道與利基，而本次會議在多方周旋下，方邀請到泰國與越南的官員來台演講，更使我們深入了解泰國與越南在核醫藥法規方面的知識與未來的方針，實則獲益良多，更方便政府在南向政策上面施行。

在此，建議如下列幾點

1. 在核醫藥品法規人才培育上，需規劃藥政人才交流訓練，籌備藥政法規教育訓練相關辦法，以培育國際化法規種子人才。
2. 在核醫藥品技術人才培育上，針對於核醫藥品管理、核醫新藥研發及創新法規政策等面向作引導，並推動國內藥政教育學以致用。
3. 在國內法規上，須建立與國內核醫藥品相關單位良好之溝通的縱向管道，並多舉辦國內核醫藥品相關研討會以加強橫向聯繫。
4. 在國際鏈結上，需能隨時更最新國際趨勢，加強與各國的聯繫，定期舉辦交流會議，培養未來國際人才之需求，提昇核醫生技

製藥產業國際競爭優勢。

伍、 參考文獻

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附錄一 會議簡報檔

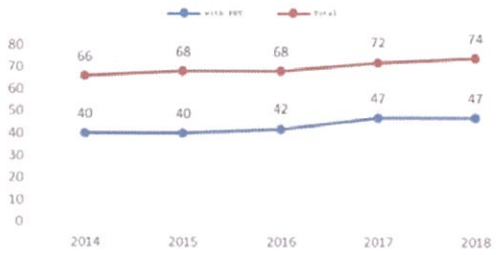
Current Status of Nuclear Medicine in Taiwan

Ruoh-Fang Yen, MD, PhD
Society of Nuclear medicine, Taiwan
National Taiwan University Hospital
2019/07/26

History of NM in Taiwan

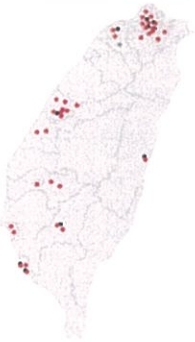
- **1955 : The radioisotope Lab. established at National Taiwan University (NTU).**
- 1956. National Defense Medical Center established the Central Atomic Medical Research Lab.
- 1957 : NTU established a thyroid uptake machine.
- 1961 : National Tsing Hua U (Taiwan) established a nuclear reactor (THOR) and provided I-131 for clinical use.
- 1965 : Taipei Veterans General Hospital (TVGH) purchased a γ-counter, a thyroid uptake machine and a linear scanner.
- **1968 : Nuclear Medicine Center first established in hospitals (TVGH and Tri-Service General Hospital).**
- 1975 : TVGH established the clinical RIA Lab.
- 1984 : Taiwan Institute of Nuclear Energy Research (INER) commercialized oral I-131.
- **1987 : Establishment of The Society of Nuclear Medicine, Taiwan (ROC).**
- 1988 : Board of Nucl. Med., Taiwan (ROC) established [1 of the 23 governmental recognized (independent) boards].
- 1993 : INER built medium sized negative charged cyclotron (EBCO, 30MeV).
- 2005 : INER provided Tc-99m TRODAT-1 and In-111 Octreotide for clinical use.
- **2006** : The governmental health insurance reimbursed PET.
- 2010 : The governmental health insurance reimbursed F-18 NaF (during Tc-99m shortage).
- **2014 : NTU and Linko CGGH installed PET/MRI (Siemens).**
- **2018 : TVGH installed PET/MR (GE SiPM).**

NM Departments



Imaging facilities and Equipment

- **Cyclotron:**
  - **Mini-cyclotron: 12**
    - **North 7**
    - **Central 2**
    - **South 2**
    - **East 1**
  - **Medium-cyclotron (30 MeV): 1**
- **PET or PET/CT: 50+**
  - **PET/MR: 3**
  - **SPECT or SPECT/CT: 113+**



Personnel

- **Society active member: 500+**
  - **NM Physician: 127**
  - **Radiological Technician: 207**
  - **Clinical Lab. Technician: 85**
  - **Pharmacist: 31**
  - **Scientists**

The trend of NM scans utilization under the coverage of NHI (2000-2012)

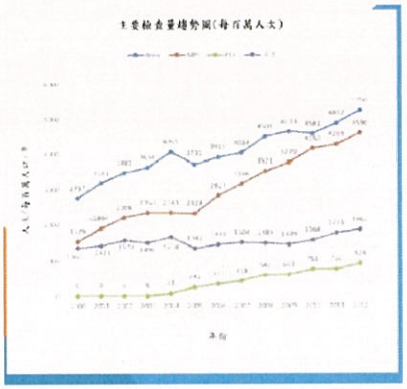
- The NM studies have been reimbursed by Taiwan National Health Insurance (NHI) since its start in 1995.
- PET scan has been reimbursed since 2006
- The number of NM scans was 251,000 in 2012, 14,638 per million people.
  - The most frequently performed studies are:
  1. Whole-body bone scan (5,250/million people, 36% of all scans),
  2. Myocardial perfusion scan (4,592/million people, 31%), and
  3. Whole-body PET scan (934/million people, 6.4%).

Utilization of nuclear medicine studies in Taiwan, 2000-2012.

Variables	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	average	%	increment
Whole body bone scan	2,757	3,181	3,492	3,634	4,065	3,731	3,915	4,034	4,501	4,633	4,581	4,892	5,259	4,051	37	176*
Stress& redistribution Myocardial perfusion study	1,529	1,896	2,206	2,350	2,343	2,328	2,827	3,166	3,521	3,770	4,150	4,269	4,590	2,996	27.4	250*
Whole body PET	-	-	-	-	71	243	333	418	587	603	755	766	924	522	4.8	100*
Ventricular ejection fraction measurement & wall motion stud	321	331	340	298	388	426	405	497	458	448	432	504	540	414	3.5	18*
Whole body inflammation scan	234	194	283	313	356	357	367	387	386	397	399	415	404	346	3.2	16*
Dynamic renal/urinary function study	306	326	294	265	274	212	212	243	267	232	214	225	188	251	2.3	-9*
Meckle's diverticulum scan	291	398	614	716	153	199	235	153	-	7	2	-	2	213	1.9	-46*
Tc99m thyroid scan	255	242	212	183	198	195	174	204	203	179	160	171	221	200	1.8	-4*
Sialoscintigraphy	101	88	115	156	172	183	196	208	225	233	242	276	326	194	1.8	17*
Whole body tumor scan	150	191	210	209	229	182	207	186	204	223	182	146	176	192	1.7	-1
I-131 cancer work-up	102	113	150	145	150	143	168	182	214	227	242	250	284	182	1.7	14*
I-131I treatment	92	122	120	117	117	133	165	174	171	186	228	191	212	156	1.4	10*
Resting cardiac function study	99	114	106	95	104	98	104	150	172	156	156	322	242	148	1.4	14*
Lung perfusion scan	160	180	151	163	224	133	145	131	117	131	93	106	65	138	1.3	-8*
Three-phase bone scan	116	92	135	120	139	132	130	129	137	146	142	142	132	130	1.2	3*
Cerebral perfusion scan	103	133	158	143	132	117	138	127	135	102	74	65	78	116	1.1	-5*
Renal scan	251	196	143	120	134	101	66	59	75	59	50	59	60	106	1	-14*
Lymphoscintigraphy	-	-	-	-	31	41	49	80	123	110	145	170	201	106	1	21*
Lung ventilation study	230	113	92	111	147	85	82	59	53	48	22	43	28	86	0.8	-12*
Venography	59	89	85	81	85	45	62	69	94	78	84	100	88	78	0.7	1
Others	490	500	364	264	629	565	550	473	463	496	624	433	446	179	3.2	4
Total	7,645	8,499	9,260	9,483	10,141	9,649	10,530	11,129	12,106	12,454	13,064	13,709	14,638	10,948	100	486

Per million population within NHI
*p < 0.05
*p < 0.01
reimbursed since 2004

Trend of NM studies in Taiwan, 2000-2012.



The utilization of radionuclide myocardial perfusion imaging and cardiac catheterization under Taiwan's universal health insurance program

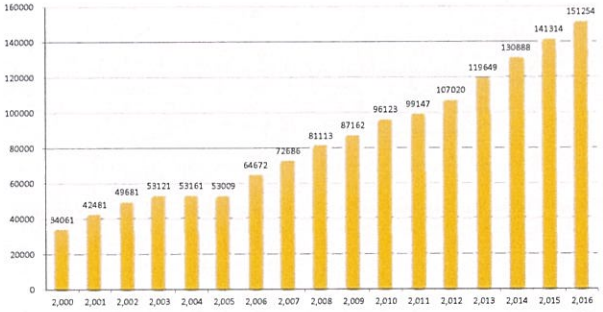
Int J Cardiovasc Imaging (2013) 29:1039–1042

Table 1 The number of CAD, MPI and cardiac catheterization in Taiwan, 2005–2009

Years	CAD		MPI	Cardiac catheterization
	Incidence case	Prevalence case		
2005	8,768	32,844	2,451	2,897
2006	7,901	32,633	2,879	3,079
2007	8,336	34,064	3,177	3,186
2008	7,635	34,097	3,573	3,694
2009	7,570	35,117	3,675	3,900

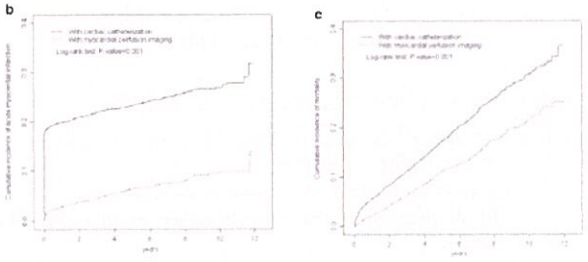
MPI may be underutilized to serve the role of gatekeeper for cardiac catheterization.

MPI



Impact of initial myocardial perfusion imaging versus invasive coronary angiography on outcomes in coronary artery disease: a nationwide cohort study

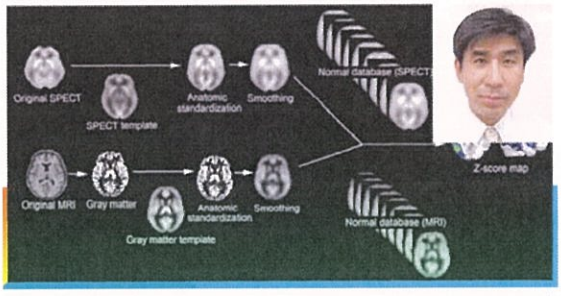
Eur J Nucl Med Mol Imaging (2018) 45:567–574



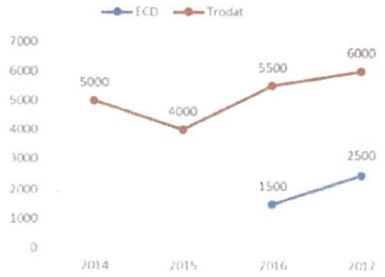
In patients with suspected stable CAD, compared with initial invasive CAG, a selective strategy guided by MPI was associated with lower rates of revascularization and MI and improved survival.

eZIS Z-score imaging system

By Prof. Hiroshi Matsuda, National Center of Neurology and Psychiatry, Japan



Brain Studies



NM studies in NTUH

NM Studies	2013	2014	2015	2016	2017	2018	
MPI	7527	7694	7885	8021	7816	7869	↔
Whole body bone	7614	7918	6763	6252	6688	6514	14%↓
FDG PET	1918	1984	1976	2265	2589	2994	56%↑
Lymphoscintigraphy	679	778	779	839	898	945	
Tc-99m Sialoscintigraphy	690	605	693	780	769	897	
TRODAT-1 Brain SPECT	199	299	257	467	496	706	X3.5↑

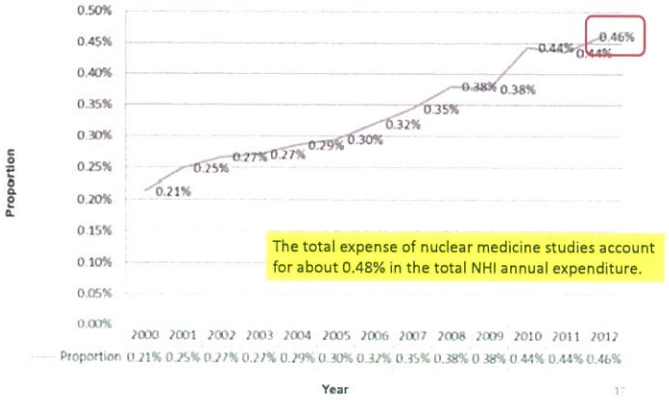
NIH coverage in FDG PET (since 2006.1.1, revised on 2010.6.1)

- Epilepsy focus detection for surgical planning
- Viable myocardium for heart failure
- Oncology (9 cancers)
  - Breast ca, lymphoma:
    - staging, therapy monitoring, recurrence detection, restaging
  - Colorectal can, esophageal ca, head/neck ca (exclude brain ca), primary lung cancer, melanoma, thyroid cancer, and cervical cancer:
    - Staging, recurrence detection, restaging
      - When CT/MRI inconclusive and state its necessity in chart
      - With intention for further aggressive treatment

Indications for FDG PET in NTUH (2019/01-06)

Lymphoma	Lung	Esophageal	Colorectal	Head/neck	Others
33%	31%	9.0%	8.6%	7.2%	11.2%

The proportion of total expense of NM study in the NHI expenditure



The total expense of nuclear medicine studies account for about 0.48% in the total NHI annual expenditure.

Cost analyses (Relative to NHI reimbursement)

	Drug	Scanner	Personnel	Total	
MPI stress/res (MIBI)*	65%	8%	9%	82%	
MPI-resting(MIBI)*	69%	4%	8%	81%	
MPI (Tl-201)*	43%	8%	9%	60%	
Bone	54%	13%	19%	86%	
Tumor (Ga-67)	77%	19%	15%	111%	←
Inflammation (Ga-67)	99%	25%	19%	142%	←
ECD Brain perfusion	59%	3%	4%	65%	
MUGA	56%	9 %	17%	83%	
Renal cortical	67%	17%	23%	107%	←
Renal (DTPA)*	41%	17%	17%	75%	
Renal (MAG3)*	109%	17%	18%	143%	←
TRODAT-1	61%	2%	6%	73%	
Sialoscintigraphy*	33%	15%	21%	69%	
Lung perfusion	56%	14%	20%	90%	

PET tracers

- NIH coverage tracers:
  - F-18 FDG
  - F-18 NaF (when Tc-99m shortage)
- TFDA approval but Non-NIH-coverage tracers:
  - Florbetaben (Amyloid agent, NeuroCeq, Piramal Imaging)
  - F-18 DOPA (PD, brain tumor)
  - F-18 FLT (Cell proliferation marker)
  - C-11 Methionine (HCC, brain tumor)
  - C-11 Acetate (HCC)
  - C-11/F-18 Choline (HCC, prostate cancer, parathyroid adenoma)
- Clinical Trial tracers:
  - C-11 PiB, florbetapia (Amyloid agent, Amyvid)
  - T-807, PBB3 (tau)
  - Ga-68 DOTATOC (Neuroendocrine tumor),
  - Ga-68 PSMA (prostate cancer)
  - .....

Therapy Radiopharmaceuticals

- NIH coverage agents:
  - I-131 (thyroid cancer)
  - Ra-223 (prostate cancer bone metastases, 2014, NHI at 2019/03)
- TFDA approval but Non-NIH-coverage agents:
  - Y-90 Microsphere (HCC, liver metastases)
- Non-TFDA approval agents:
  - I-131 MIBG (pheochromocytoma, neuroblastoma)

Problems we face

- NHI reimbursement hasn't been adjusted since 1995, but
  - the price of radiopharmaceuticals and scanners have been increased significantly
- Under-utilization of nuclear medicine studies
  - especial PET scan
    - ~1500/million population in Taiwan
    - ~5000/million population in Japan
      - Physicians hesitate to use PET scan because of worrying about the reimbursement been cut by NHI
- Regulation of TFDA
  - The license of some existing drugs have been suspended while new drugs can't come in due to long and tedious process
  - NM drugs should not treated the same as ordinary drugs

Thank you for your attention!

- References

  - Huang YY, Hung MC, Lin LF, Cheng CY. The Utilization of Nuclear Medicine Studies and the Dilemma in Taiwan: A Brief Report. Ann Nucl Med Mol Imaging 2016;29:166-178
  - Nishiyama Y, Kinuya S, Kato T et al. Nuclear medicine practice in Japan: a report of the eighth nationwide survey in 2017. Ann Nucl Med 2019 June epub.
  - Lin MC, Yen RF, Chen HY et al. The utilization of radionuclide myocardial perfusion imaging and cardiac catheterization under Taiwan's universal health insurance program. Int J Cardiovasc Imaging 2013; 29:1039–1042
  - Hung GU, Ko KY, Lin CL, Yen RF, Kao CH. Impact of initial myocardial perfusion imaging versus invasive coronary angiography on outcomes in coronary artery disease: a nationwide cohort study. Eur J Nucl Med Mol Imaging 2018; 45:567–574

Regulations of Nuclear Medicines in Taiwan

Mei-Chen Huang
Taiwan FDA
July 26, 2019

衛生福利部 食品藥物管理署 Food and Drug Administration

http://www.fda.gov.tw/

Outline

- **Regulations for Radiopharmaceutical Drugs**
  - Definition, Regulations
  - Documents Required for the Registration
- **Review Process of Radiopharmaceutical Drugs (NDA)**
- **Statistics of the Approved Radiopharmaceutical Drugs in Taiwan**
- **Regulations for Positron Emission Tomography (PET) Radioisotopes**
- **Future Prospects**

Radiopharmaceutical Drugs

- **Definition:**

  Drugs containing radioactive substances for human uses. After being administrated to humans, the drug can diagnose, monitor, treat, alleviate disease conditions or achieve other medical effects.

[Article 4, Regulation for Registration of Medicinal Products]

Radiopharmaceutical Drugs

- **Composition:**
  - a radionucleotide (e.g., technetium-99m, iodine-131,etc.)
  - a nonradioactive pharmaceutical
- **Applications:**
  - for diagnostic purposes
  - for therapeutic purposes

Regulations for Radiopharmaceutical Drugs

ICH guidelines are adopted in Taiwan

Law	**Pharmaceutical Affairs Act**
Regulation	**Regulation for Registration of Medicinal Products** Regulations on Human Trials Regulation on Good Clinical Practice (GCP) Regulation on Good Manufacture Practice (PIC/S GMP)
Guidance	Guideline on Clinical Trials of Radiopharmaceutical Drugs Guideline on the Assessment of Radiopharmaceutical Drugs

Regulations for Radiopharmaceutical Drugs

- **Registration:**
  - Information that should be submitted with the application for drug registration of radiopharmaceutical drugs are as specified in **Appendices 10 and 11**.
  - The application should comply with the **Guideline on Clinical Trials of Radiopharmaceutical Drugs** and the **Guideline on the Assessment of Radiopharmaceutical Drugs** as announced by the central health competent authority.
  - **Regulations for new drugs** stipulated in this Chapter are also applicable to radiopharmaceutical drugs with **new dosage forms and new doses.**

[Article 43, Regulation for Registration of Medicinal Products]

Documents Required for Registration (1/2)

[Appendix 10, Documents Required for the Registration of Radiopharmaceutical Drugs]

1. Application fee (NTD 150,000-800,000)
2. Application form
3. Assurance statement
4. Form for sticking label and package insert
5. Authorization letter (for imported products)
6. Certificates of Pharmaceutical Product (for imported products)
7. Formulation basis (for local products)
8. GMP certificate
9. Testing specifications, methods and results of API
10. Testing specifications, methods and results of excipients
11. Testing specifications, methods and results of final products
12. Manufacturing and control standard or batch records of the tentative production batch
13. Validation documents of analytical methods
14. Validation documents of critical manufacturing processes
15. Documents of stability study
16. Technical documents **(as listed in Appendix 11)**

Documents Required for Registration (2/2)

[Appendix 11, Technical Documents Required for the Registration of Radiopharmaceutical Drugs as NEW DRUG]

- **Description**
  - Properties and a comparison with other drugs, uses in other countries, origin, discovery process, etc.
- **Specification**
  - Testing methods and specifications of physicochemical properties
- **Non-clinical animal study reports**
  - Safety report, efficacy report, PK report
- **Clinical trial reports**
  - Design and results of clinical trials
  - Literature review and citation
- **Radiation dosage study reports**

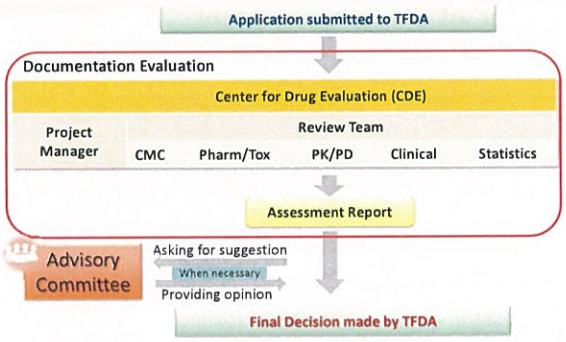
For the detailed requirements of each kind of applications (New ingredient for diagnosis/treatment, New administration route, New indication, New dosage form, New dose), **please refer to the checklist of Appendix 11.**

Review Process of Radiopharmaceutical Drugs (NDA)

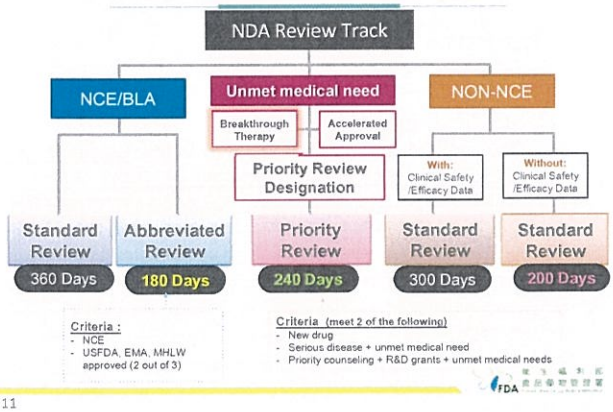
衛生福利部 食品藥物管理署 FDA Food and Drug Administration

http://www.fda.gov.tw/

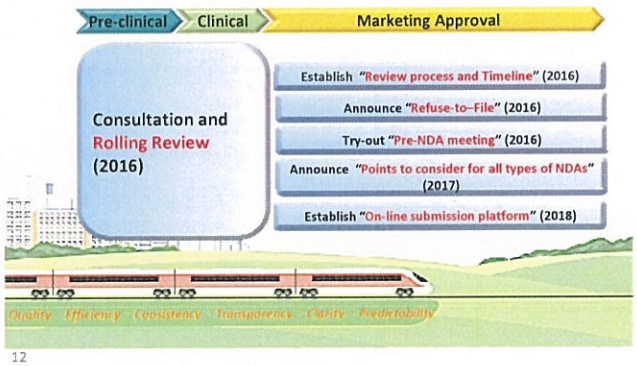
Review Process of Radiopharmaceuticals (NDA)



Expedited Review Pathways for NDA

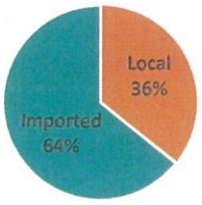


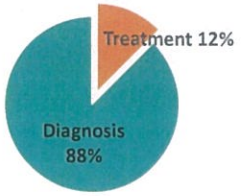
Enhancing Review Efficiency



Statistics of the Approved Radiopharmaceutical Drugs in Taiwan

Total: 56





Statistics of the Approved Radiopharmaceutical Drugs in Taiwan

Drug name	Manufacturer	Indication
Iodine-131 Oral Solution "INER"	INER (Taiwan)	Thyroid dysfunction
Sodium Iodide (131-I) Therapy Capsules	ANSTO Health (Australia)	Hyperthyroidism; Thyroid cancer
PPhB Sodium Iodide (131-I) Capsules	PET Pharm Biotech (Taiwan)	Thyrotoxicosis; Hyperthyroidism; Thyroid cancer
Xofigo Solution for Injection	Bayer/ Institute for Energy Technology (Norway)	Castration-resistant prostate caner
Sodium Iodide (I-131) Oral Solution	ANSTO Health (Australia)	Hyperthyroidism; Thyroid cancer
Sodium Iodide Na 131-I POLATOM capsules	National Center for Nuclear Research (Poland)	Hyperthyroidism
Capsion 50-3700 MBq Capsules	Cis Bio International (France)	Hyperthyroidism

Food and Drug Administration, Ministry of Health and Welfare

Regulations for Positron Emission Tomography (PET) Radioisotopes

衛生福利部 食品藥物管理署 Food and Drug Administration

http://www.fda.gov.tw/

Positron Emission Tomography (PET) Radioisotopes (PET Drugs)

Short half-life V.S Long transport distance

PET center in 9 hospitals

NTUH, TVGH, TSGH, SKMH, LKCGMH
CSMUH, YGH, E-DAH,HTCH

1 Pharmaceutical company

Compounding
【Direction and Guideline for PET Radioisotopes Compounding】

Manufacturing
【PIC/S GMP】

Under TFDA's inspection

Direction and Guideline for PET Radioisotopes Compounding

revised in 2015.09.14/2019.04.02

- Referred to PET Drugs-CGMP (US FDA), ensure the safety and quality of PET radioisotopes
- Only applicable for the radioisotopes with short half-life (e.g. F-18, 109.8 mins, C-11, 20 mins, N-13, 9.96min, etc)
- can be compounded in the PET centers with physician's prescription
- Need professionally trained operators and pharmacists

Direction and Guideline for PET Radioisotopes Compounding

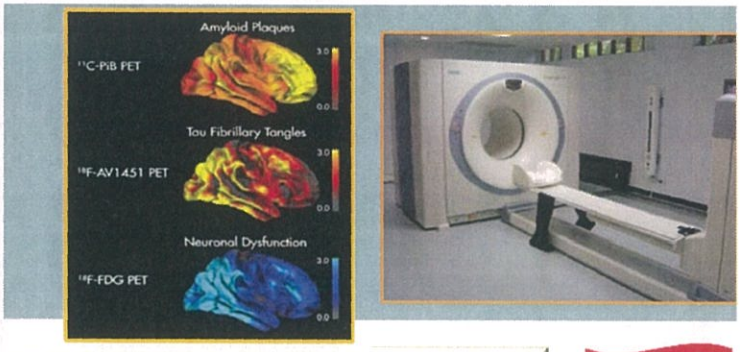
- **Must be produced according to Quality Standards/Requirements in the Direction and Guideline :**
  - Facilities and equipment
  - Raw materials, container and cap seal
  - Compounding process
  - Laboratory
  - Quality control of final product and release
  - Labeling and packaging
  - Transportation
  - Complain
  - Record
- **Currently available items:** F-18-FDG, F-18-FDOPA, F-18-NaF, C-11-Sodium Acetate, N-13-NH3, F-18-FLT, F-18-FCH, Ga-68-DOTATOC

Future Prospects

- **Continuously revise/update the regulatory requirements to be inline with international standards:**
  - Guideline on the Assessment of Radiopharmaceutical Drugs
  - Guideline on Clinical Trials of Radiopharmaceutical Drugs
  - Direction and Guideline for PET Radioisotopes Compounding
- **Facilitate the development of radiopharmaceutical drugs**

Thank you for your listening!

衛生福利部
食品藥物管理署
Food and Drug Administration
http://www.fda.gov.tw/



USE OF NUCLEAR MEDICINE IN THAILAND 2019

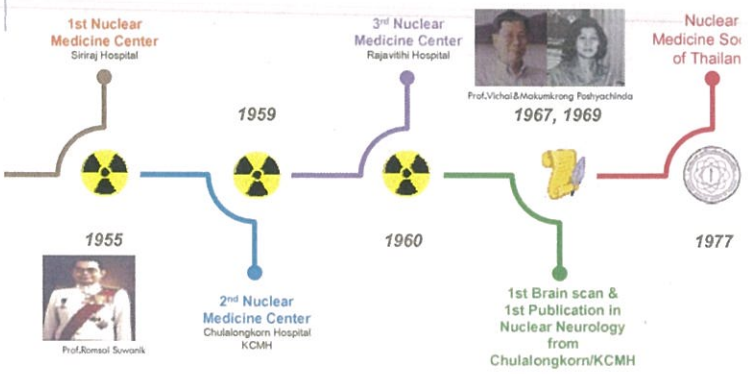
SIRIRAJ HOSPITAL 188

HISTORY

1st NM center in Thailand was in Bangkok, Siriraj Hospital 1955
Established by
Professor Romsai Suwanik

Society of NM of Thailand was established in 1977
120 members

HISTORY OF NUCLEAR MEDICINE & NUCLEAR NEUROLOGY IN THAILAN



Prof Romsai

sidents of THAI SNM

Prof. Makumkrong

Prof Sombat

Prof Vacharee

Prof Vacharin

Yuthana Saengs

THAI SNM 2019

UP TO DATE THAI SNM 2019

- **Current THAI SNM members : 375**
- **95 NM physicians, the rest are physicist, technologist, radiochemist/pharmacist, nurse**
- **Current activities : 2 regular scientific meetings in March and December**

NUCLEAR MEDICINE CENTERS IN THAILAND

Government hospitals 22

University hospitals – 9 (5 residency training centers)

Non-university general hospitals – 8

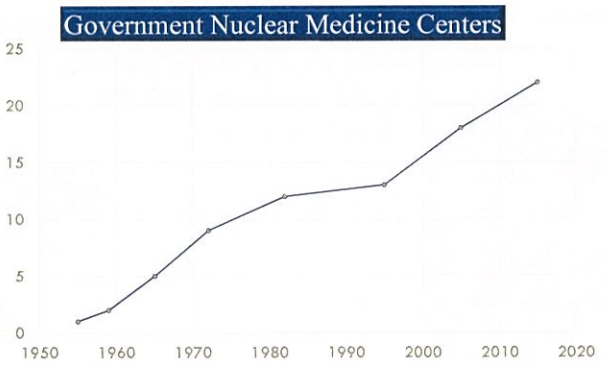
Non-university cancer hospitals - 5

Private hospitals 7

General hospitals – 4

Cancer hospitals – 3

Total 29 centers



DISTRIBUTION MAP

77 PROVINCES

POPULATION 69 MILLIONS

BKK 8,597,808 (12%)

TOTAL 29 NM CENTERS

BKK 16 (55%)PROVINCIAL 13 (45%)

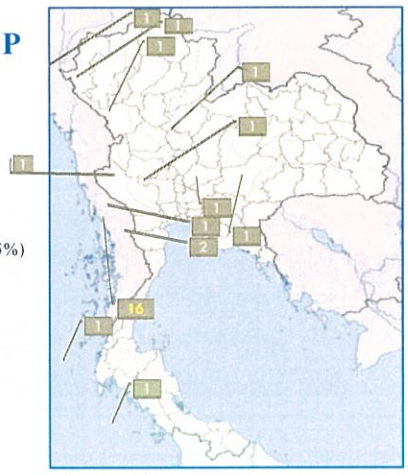
2 CENTRAL

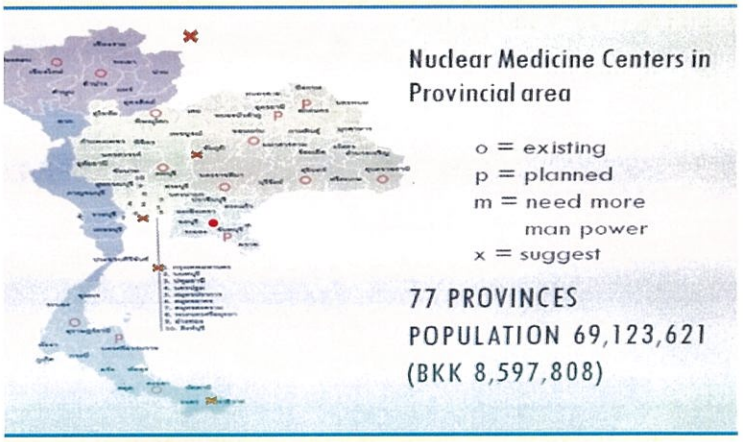
3 NORTH

2 SOUTHERN

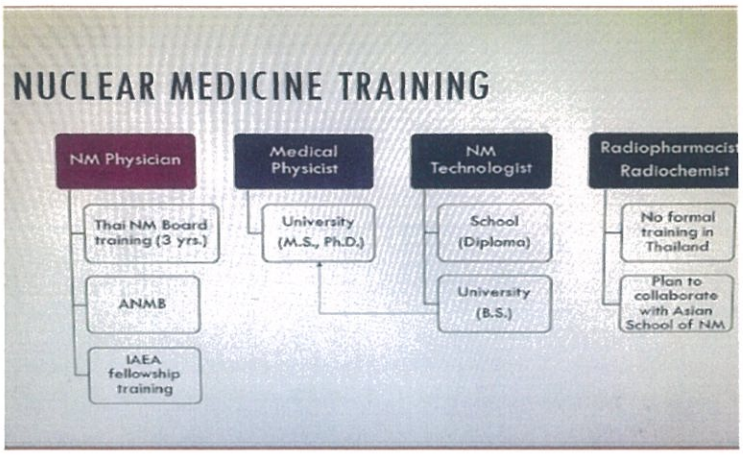
4 NORTHEAST

2 EAST





NUCLEAR MEDICINE TRAINING



ATIONAL HEALTH CARE SCHEME AND REFERRAL SYSTEM

Base on type of national health care coverage

- Government/ State enterprise/Bangkok metropolitan officers /Military 2.2 million
- Social security scheme for employees 13 million
- Universal health coverage scheme for Thai people at registered hospital near habitation or hometown 54 million

Base on type of national hospital referral system

*Refer patient from primary to secondary to tertiary and supertertiary hospital

PERSONNEL

Job	Number
Physician	95
Physicist	29
Technologist	106
Nurse	59
Pharmacist	15
Chemist	17
Scientist	3
Others	47
Engineer	3
Neurologist	1

EQUIPMENT IN 25 CENTERS

Equipment	Number
Gamma Counter	12
Gamma Probe	12
Rectilinear scanner	0
Static gamma detector	8
Planar gamma camera	1
SPECT gamma camera	27
SPECT/CT gamma camera	16
Cardiac SPECT	2
PET-CT scanner	11
PEM	1
Cyclotron	4
Dose calibrator	10
Survey meter	7
Bone densitometer	10
Wipe test	2
Contamination Survey meter	2
Chemiluminescent	2
TLC counter	1

STATISTICS PET/CT AND POPULATION

Thai population are 69 millions, 11 machines , so the rate of one PET/CT is for **6.27** million population

South Korea

is one of the leading countries in Asia for the number of PET/ CT with 148 machines

The rate of one PET/CT is for **0.32** million population

(RAS 6061/9001/01,IAEA/RCA)

STATISTICS PET/CT AND POPULATION

Thai reimbursement PET/CT study cost is only for government officer sector

***Only for 2 indications approved for reimburstment** due to limited government budgets :

- 1 Non small cell lung cancer with staging for curative surgery
- 2 Suspected recurrent colon cancer with negative study from CT and MRI

THAI SNM : have submitted 9 more indications for reimbursement from the government sector but has not been approved .

*Ongoing universal coverage for Thai people policy will intensively accepted for treatment in **Lymphoma** and on process of cost benefit and effectiveness evaluation

NUCLEAR MEDICINE 59455 STUDIES IN THE YEAR 2016

The top five studies :

Bone scan 47.5%,
Total body scan (I131) 12.3%,
Cardiac scan 11.3%,
PET oncology 9.3%
Thyroid scan 7.5%

These five studies composed of 87.9% .

NM TREATMENT IN 25 CENTERS

Treatment	Number	
Thyroid malignancy	3566	28.8%
Hyperthyroidism	8658	70.2%
Polycythaemia vera	2	
Bone metastases (Sm153-EDTMP, Ra-223)	41	
Synovitis	10	
Other: e.g. Y-90 microspheres, I-131 MIBG,	61	

NUCLEAR MEDICINE RESIDENCY TRAINING

Started in 1988 with 5 university medical institutes for 3 years training course

***Thai Board of Nuclear Medicine** set up by Thai Board Committees of Nuclear Medicine and under Royal College of Radiologist of Thailand

Exams: Thesis, MCQ basic and clinical aspect, oral and cases

NM BOARD COMMITTEES 2019

Service

IAEA

Quality Management Audits in Nuclear Medicine (QUANUM)

Education

World Federation of Medical Education (WFME)

INTERNATIONAL STANDARDS

CYCLOTRONS IN THAILAND

Chulabhorn National Cyclotron GE 2006
BDMS Hospital ACSI 2006
Siriraj Hospital Sumitomo 2014
Chiangmai University Hospital Sumitomo 2014
ɔcoming Cyclotron:
TINT : Rosatom (Russia)
nctioning in 2021 at Ongkharak

Chulabhorn hospital

NATIONAL CYCLOTRON AND PET CENTRE (NCPC)

Data courtesy of National cyclotron and PET Center, Chulabhorn Hospital

BDMS HOSPITAL

WATTANOSOTH HOSPITAL
BANGKOK CANCER HOSPITAL

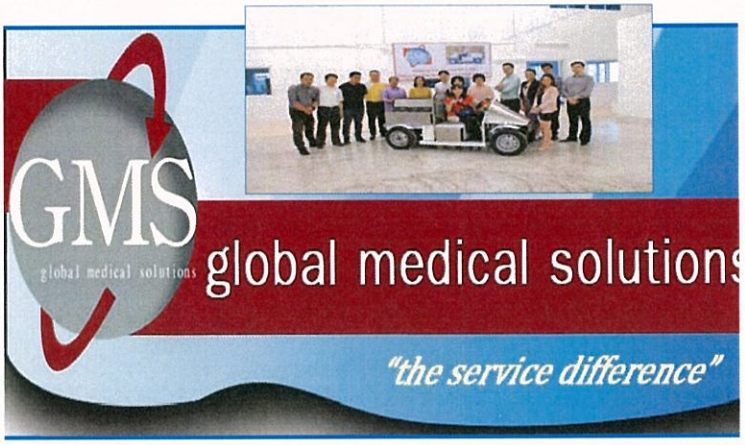
SIRIRAJ HOSPITAL

FICE OF ATOMS FOR PEACE :TO REGULATE SAFETY ILIZATIONS OF RADIATION AND NUCLEAR MATERIALS.

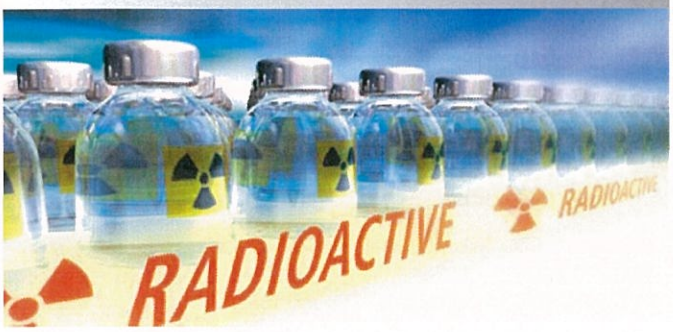
THAILAND INSTITUTE OF NUCLEAR TECHNOLOGY (TINT)

BANGKOK, SEP7/2017 — ROSATOM (RUSSIA) AND KINETICS CORPORATION LTD. (THAILAND) WILL SUPPLY A CYCLOTRON COMPLEX WITH RADIOCHEMICAL LABORATORIES FOR THE THAILAND INSTITUTE OF NUCLEAR TECHNOLOGY (TINT)

Cyclotron 30 Mev proton energy at Ongkharak 5400 square meter

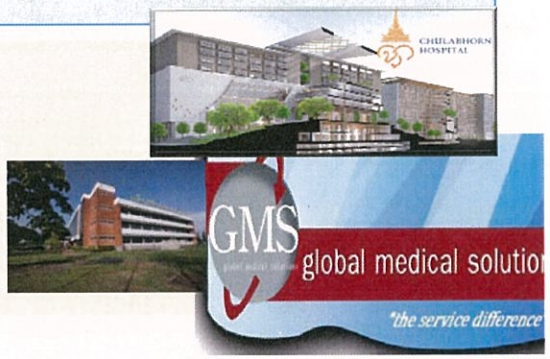


RADIOPHARMACEUTICALS



SUPPLIER FOR RADIOPHARMACEUTICALS

* TINT
* GMS
* Biogenetech
* BDMS
* Chulabhorn
* Biomedia



TECHNETIUM UNIT DOSE

Radiopharmaceuticals	Supplier	
	TINT	GMS
^{99m}Tc-DISIDA	√	√
^{99m}Tc-DTPA	√	√
^{99m}Tc-ECD	√	√
^{99m}Tc-Hynic-TOC	√	
^{99m}Tc-MAA	√	√
^{99m}Tc-MAG_3	√	√
^{99m}Tc-MDP	√	√
^{99m}Tc-MIBI	√	√
^{99m}Tc-Sulfur Colloid		√
$^{99m}TcO_4$	√	√
^{99m}Tc-Phytate	√	√

TECHNETIUM GENERATOR

Producer	Supplier
IS/France	Biogenetech
Poland	Biogenetech
entech/Australia	GMS
allinckrodt/Netherland	GMS

ON-TECHNETIUM

Radiopharmaceuticals	Supplier			BDMS	
	TINT	GMS	Biogenetech	Wattanosoth	Chulabhorn
F-18 FDG				√	√
C-11 PIB (Amyloid)				√	√
F-18 THK 5351 (Tau)					√
F-18 FDOPA				√	√
F-18 NaF				√	
Ga-67 citrate		√			
Ga-68 DOTATATE	√				available
Ga-68 PSMA					available√
I-131 Diag Capsule	√	√			
I-131 MIBG for Diagnostic	√				
I-131 Hippuran	√				
In-111 Octreo Scan		√			
Tl-201 chloride		√			

PSMA

THERAPEUTIC RADIOPHARMACEUTICALS

adiopharmaceuticals	Supplier				
	TINT	GMS	Biogenetech	Wattanosoth	Chulabhorn
31 Therapatic psule	√	√			
31 MIBG for atment	√				Lu177 dotatate Lu177 PSM
-153 EDTMP	√	√			
89 chloride		√	√		
90 Microsphere		√			
90 citrate colloid			√		BIOMEDIA
-223 chloride		√			

COLD KITS

Pharamceuticals	Supplier			
	TINT	GMS	Biogenetech	In-House
DISIDA	√			
DMSA	√			
DMSA (V)	√			√
DTPA	√			√
EC	√			
ECD	√			
HSA		√		√
Hynic-Toc	√			
Leukocyte		√		
MAA	√			
MAG_3	√			
MDP	√	√	√	√
MIBI	√		√	
Rhenium Sulfide			√	
Phytate	√			
PYP		√		√
Stannous	√	√		√

PET STUDIES IN 8 CENTERS IN 2015

PET	Number	
Oncology	5529	94%
Brain	161	2.7%
Cardiology	2	
Infection	9	
Bone	181	3.1%

LEADERS OF NM CENTERS IN THAILAND

1 Siriraj university hospital

2 King Chulalongkorn Memorial university hospital

3 Chulaborn hospital

4 -5-6 Rama, Chiangmai , Khonkhaen university hospitals

IRIRAJ HOSPITAL

223 hospital beds

30 buildings

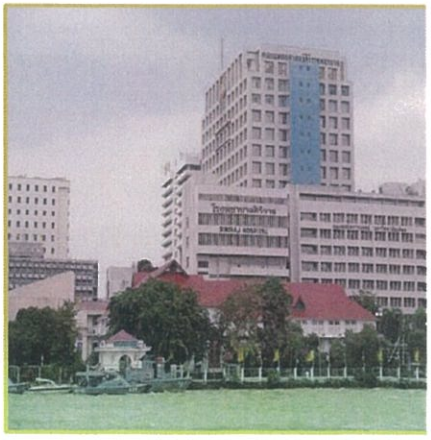
5 millions OPD visits

90,000 IPD admissions

908 full time physicians

4327 employees

Undergraduate, postgraduate, esident and fellow training



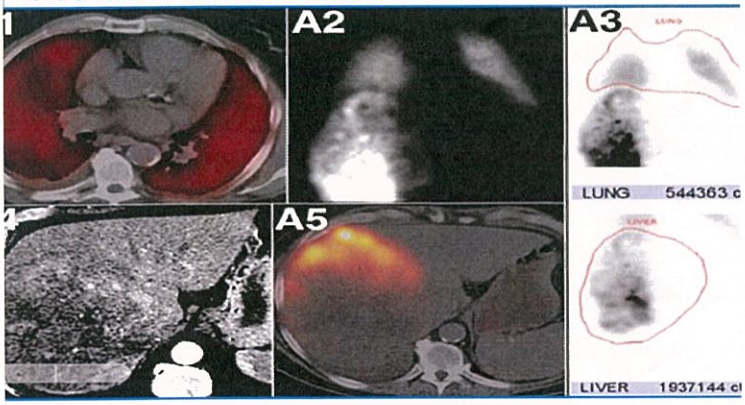
NM SIRIRAJ HOSPITAL

10 PHYSICIANS
1 Cyclotron
2 PET/ CT
4 SPECT/CT 1 SPECT
1 SPECT CZT
7000 NM imaging/Y
13000 NM thyroid/Y
25000 NM lab
500 PET CT cases

^{90}Y RESIN MICROSPHERES IN HEPATOCELLULAR CARCINOMA

- *Experiences*
  - ^{99m}Tc-MAA hepatopulmonary scan 20 cases
  - ^{90}Y resin microspheres 15 cases
- *Dose calculation*
  - Method - Partition model
  - Software - Dosimetry Toolkits (GE healthcare)
- *Research*
  - Comparison of LSF (planar VS SPECT/CT)
  - Treatment outcome

Y 90 RESIN MICROSPHERES



f. Dr. HRH
ncess Chulabhorn

NATIONAL CYCLOTRON and PET CT CENTER 2006

NCPC CHULABHORN HOSPITAL

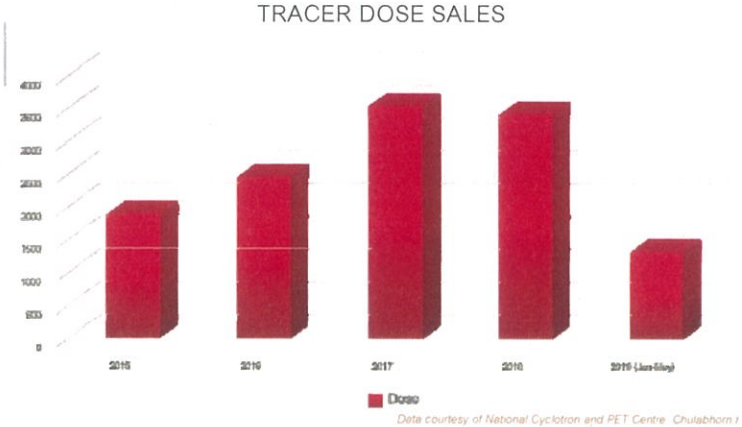
1 CYCLOTRON 1 PET CT 1 SPECT CT
3 DOCTORS

RP PRODUCTION

^{18}F-FDG
^{18}F-FDOPA
^{11}C-Choline
^{11}C-Erlotinib
^{11}C-PiB
^{18}F-THK-5351
18F-FLT
^{68}Ga-PSMA

2015 Tracer dose sell 1874 doses
2016 Tracer dose sell 2448 doses
increase 30.6%

TRACER DOSE SALES



Data courtesy of National Cyclotron and PET Centre, Chulabhorn I

CHULABHORN ROYAL ACADEMY

NATIONAL CYCLOTRON AND PET CENTRE

Diagnostic Radiopharmaceuticals		Therapeutic Radiopharmaceuticals
^{18}F-FDG	^{18}F-FDOPA	^{177}Lu-DOTATATE
^{18}F-THK5351	^{18}F-FLT	^{177}Lu-PSMA
^{11}C-CHOLINE	^{11}C-ERLOTINIB	
^{68}Ga-PSMA-11	^{11}C-PIB	
^{18}F-PSMA-1007	^{68}Ga-DOTATATE	

• Future ^{15}O-WATER

PET CT CASES INCREASE 100%

PET/CT

10 cases PET CT in 2016

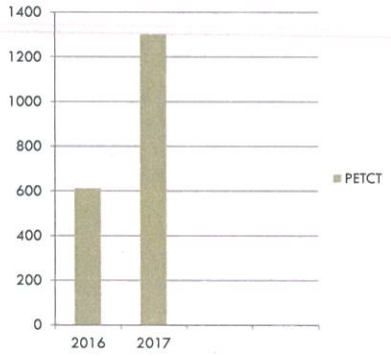
297 cases PET CT in 2017

On sale 50% price

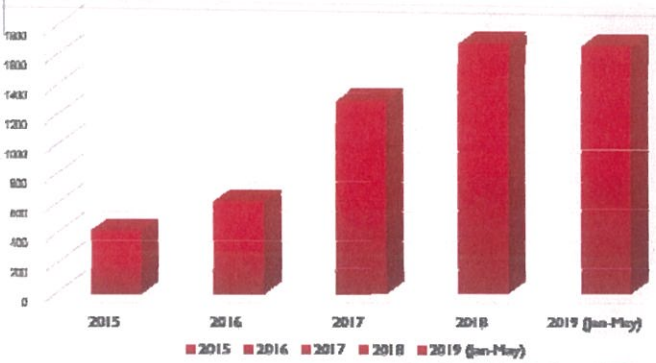
from 40,000 to 20,000 baht

(36,000 to 18,000 Taiwan D)

Up to 2019

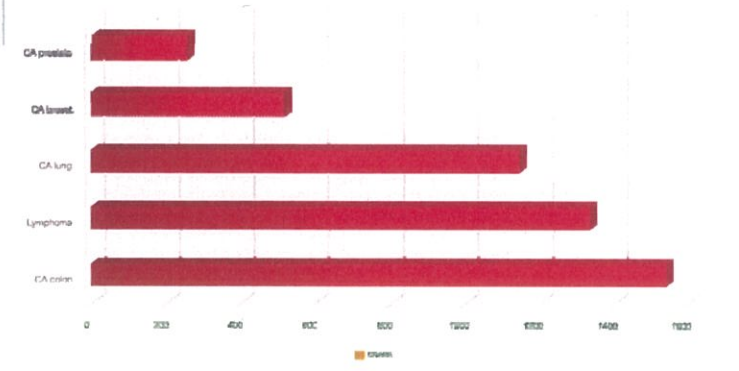


PET/CT CASES

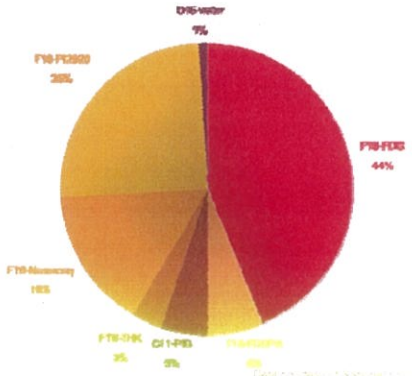


Data courtesy of National Cyclotron and PET Centre, Chulabhorn H

TOP 5 IN PET/CT CASES



RADIOPHARMACEUTICAL FOR PET/CT BRAIN (JAN-MAY 2019)



****THERANOSTICS****

Diagnostic imaging with Ga68 dotatate and PSMA since Dec2017

Radionuclide therapy with Lu177 dotatate and PSMA since April 2018

THERAPEUTIC

- Lu177-PSMA 10 cases
- Lu177-Dotatate 4 cases
- Y-90 microsphere 47 cases/year
- Ra223 2 cases

Data courtesy of National Cyclotron and PET Centre Chulabhorn hospital

O15-WATER

O15-water myocardial perfusion 3 cases

O15-water Brain 2 cases

Advantage

Short half life -> can be perform consecutive stress and rest data acquisition.

Clinical protocol can be complete within 30 minutes.

High sensitivity.

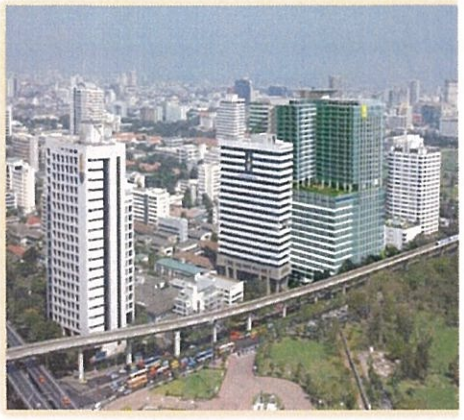
Free diffusion across capillary and cell membranes.

High extraction fraction -> provide accurate quantification of myocardial blood flow.

Low radiation exposure.

ING
IULALONGKORN
EMORIAL
)SPITAL

CMH



KCMH

University hospital

Undergraduate, postgraduate resident and fellow training

6 physicians

No cyclotron

1PET CT 2 SPECT 2 SPECT CT

4000 NM imaging/y

270 PET CT cases/y

NM KCMH HOSPITAL:

THERANOSTICS

Targeted Radionuclide Therapy in metastatic castrate- resistant prostate cancer using Lu 177 PSMA

KCMH THERANOSTIC TIMELINE

Coming Soon

First dose ^{225}Ac-DOTATATE

Targeted alpha Px

Jun

st dose

u-HADOTATATE

2019

31 May First dose ^{68}Ga-HADOTATATE

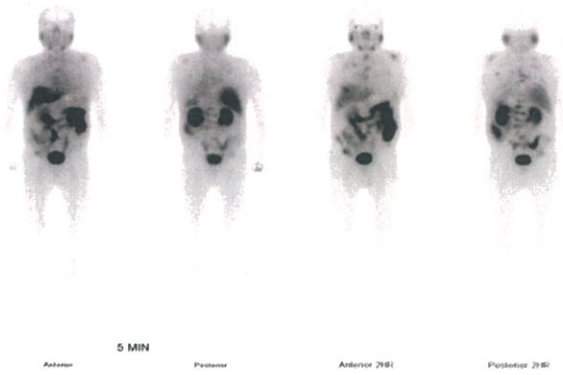
2018

24 Apr First dose ^{68}Ga-PSMA

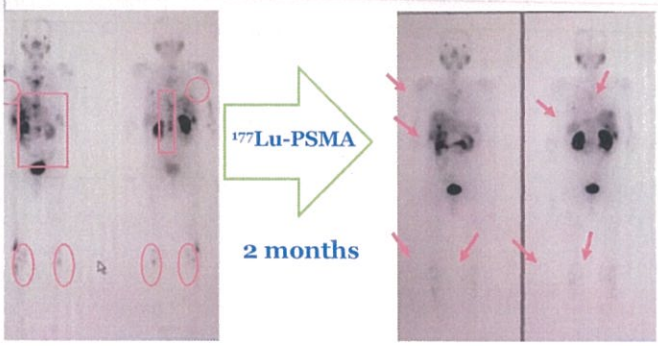
14 Feb First dose ^{177}Lu-PSMA

KCMH Patient

1st Lu-177 PSMA 120 mCi. on 14 Feb 2018



A CLINICAL RESULT IN KCMH



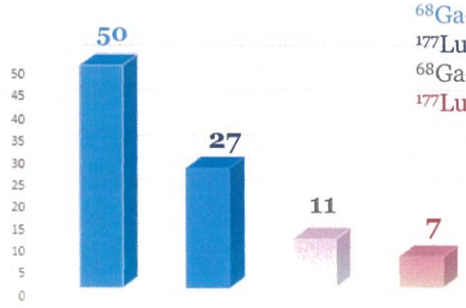
THERANOSTICS PRRT LIGANDS

Ga68 dotatate diagnosis of neuroendocrine tumor

Lu177 dotatate treatment in neuroendocrine tumor

1st case in June 2018

THERANOSTIC AT KCMH



^{68}Ga-PSMA
^{177}Lu-PSMA
^{68}Ga-HADOTATATE
^{177}Lu-HADOTATATE

Update July 14, 20:

Nuclear Medicine Neuroimaging in Thailand

Where are we now?

FROM THE PAST 1955

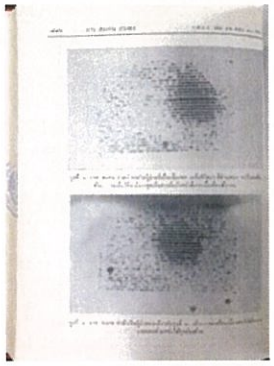
Early Phase: Planar 1960's

ISTORY OF UCLEAR NEUROLOGY

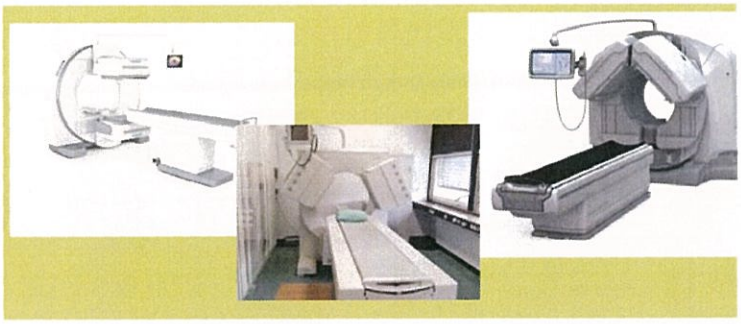
- Brain scan started at Chulalongkorn University (Chulalongkorn Hospital, KCMH)

since June 1, 1967

- Rectilinear scanner
- Hg-203
- 625 cases/2 years

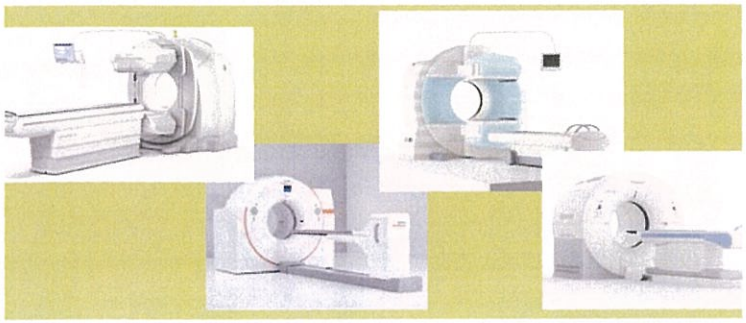


Suwanwela C, Poshyachinda V, Poshyachinda M, Suwanwela N. Radioisotope scanning of the br
J Med Assoc Thai 1969;52(10):812-831



TRANSITION

Emerging SPECT 1980's



NEW AGE

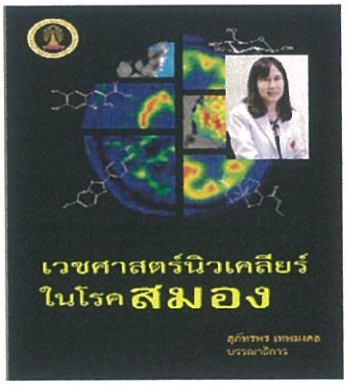
SPECT/CT PET/CT

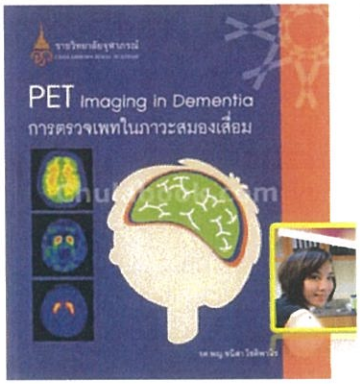
NATIONAL BRAIN PROJECT BY NM TECHNICS

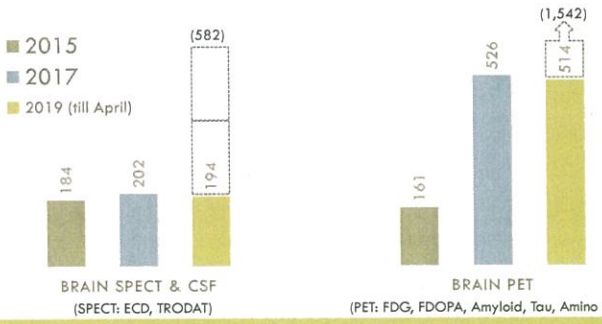
Associated Prof Supatporn
From KCMH

Brain studies are growing in NM centers of Thailand as of many Asian countries

Dementia, Epilepsy, Cerebrovascular disease, Parkinson disease, etc.







NUCLEAR NEUROLOGY STUDIES

SCOPE OF THE COURSE :

- BASIC CLINICAL NEUROLOGY IN DEMENTIA AND EPILEPSY
- NEUROIMAGING PROTOCOL AND TECHNIQUE
- IMAGE INTERPRETATION:
  - QUALITATIVE ASSESSMENT
  - QUANTITATIVE ANALYSIS USING APPROPRIATE SOFTWARE
- UPDATE IN RADIOPHARMACEUTICALS IN NEUROIMAGING STUDIES

FOREIGN CONTRIBUTORS : IAEA

ADEMIC ACTIVITIES TO PROMOTE NUCLEAR NEUROLOGY

- Nuclear Neurology meetings & workshops
  - 1st National training course in Nuclear Neurology at KCMH (Nov 2017)
  - 2nd National training course in Nuclear Neurology: SPM course at KCMH (May 2018)
  - International training course & workshop: Neuroimaging and brain mapping in dementia and epilepsy at Siriraj Hospital (May 2019)

ROJECTS & ACTIVITIES TO PROMOTE NUCLEAR NEUROLOG AT NATIONAL LEVEL

- IAEA-RCA project RAS 6083 (year 2016-2018): National training courses
- IAEA-TC project THA 6043 (year 2016-2019): Fellowship, scientific visit, training courses, guideline development
- IAEA project RAS 6091(year 2018-2020): Short-term fellowship training
- MOU between THAI SNM & JSNM in 2016: eZis software
- Workforce to get reimbursement for Nuclear Medicine procedures
- Thailand Clinical practice guidelines & procedure development (2019-2020) start on 1st meeting July2,2019

THAI SNM COLLABORATIONS:

- International Atomic Energy Agency (IAEA)
- Asian Regional Cooperative Council for Nuclear Medicine (ARCCNM), Asian School of Nuclear Medicine, AOFNMB
- World Federation of Nuclear Medicine and Biology (WFNMB)
- **MOU with Japanese Society of Nuclear Medicine (JSNM)**
- **MOU with Taiwan Society of Nuclear Medicine (TSNM)**
- **MOU with INER (institute of nuclear energy research)**

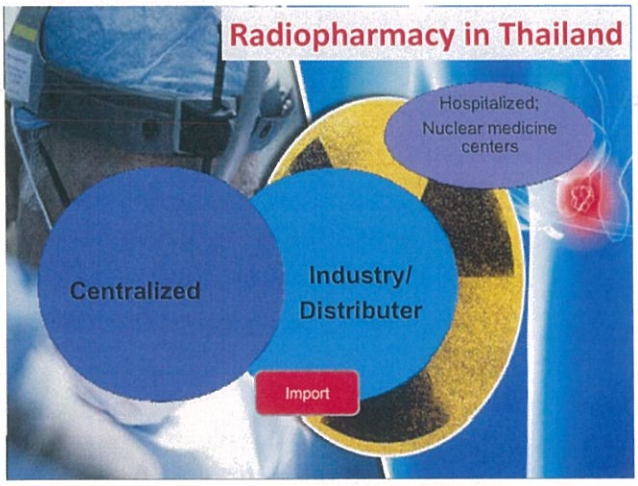
Overview of Regulatory Framework of Radiopharmaceuticals in Thailand

Achiraya PRAISUWAN, Pharm D.
Professional Pharmacist, Lead GMP Inspector
Bureau of Drug Control, Thai FDA

Outline

- Radiopharmacy in Thailand
- Regulatory Framework
- Regulations
- Future Plan

Radiopharmacy in Thailand



Radiopharmacy in Thailand

Office of Atoms for Peace; OAP Thailand

- licenses the possession and use of Radioactive material

Bureau of Drug Control, Thai FDA

- Pre-clinical and Clinical Trials
- Marketing Approval
- New Drug Application (NDA)
- Manufacturing process

Responsibilities of the Thai FDA about Radiopharmaceuticals (RPs)

Supervision of activities in the field of RPs supplies, organization and administration of the notified guidelines, including guidelines processes governing the production, importation, transport and storage, distribution, supply of drug procedures.

Implementation of the guidelines communicated by all natural or legal persons active in the field of radiopharmaceuticals and institutions and centers engaged in production and importing RPs

Regulatory Framework

Regulatory Framework

Medical Care or Clinical Research

- Personalized medicine; Hospital exemption

Commercialization

- Import/Manufacturing License
- Marketing Authorization
- GCP, GMP, GDP

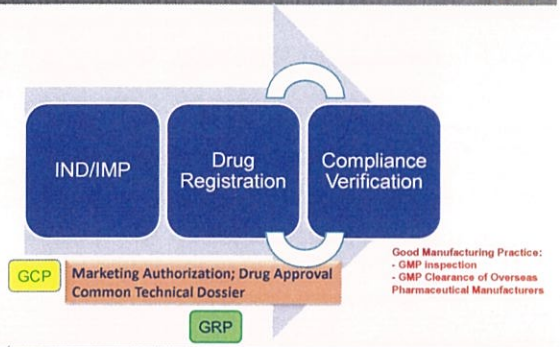
Regulatory Framework

Medical care or Clinical Research

•Hospital and clinical research exemption: Drug Act B.E. 2510 Section 13 (2)

"production of drugs in accordance with the prescription of a practitioners of medicine or practitioners of the healing arts for a particular patient" and "importation by ministries, sub-ministries and departments which have a duty to prevent or treat disease".

Regulatory Framework



Regulations

Regulations

- 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 PIC/S
- PIC/S Guide to Good GMP PE 009-12; specific Annex 3 Manufacture of Radiopharmaceuticals

Regulations

Imported products

Thai FDA Notification on GMP Clearance of Overseas Pharmaceutical Manufacturers B.E. 2560

Pharmacovigilance and product safety monitoring program

Drug Submission of RPs

Radiopharmaceuticals were submitted as Abbreviated new drugs (ANDS) example:

- ^{18}F-FDG
- Radium-223 (Xofigo®)

Production of Radiopharmaceuticals Regulatory Procedure

- Establishment of production site License
- Registration Application of RP Product
- Submission of CTD
- Establishment of the Registration Certificate is valid for 7 years

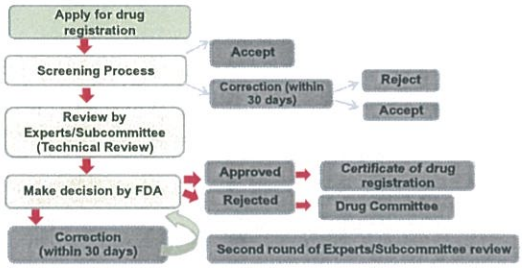
GMP Inspection

- Establishment of GMP Certificate is valid for 3 years
- Re-Inspection Process by using Risks based approach

Import of Radiopharmaceuticals Registration Procedure

1. Registration Application of imported RP Product (needs license from OAP)
2. Drug Importing Application Form
3. Registration Application of RP Product / Submission of CTD
4. GMP Compliance Verification: GMP Clearance of Overseas Pharmaceutical Manufacturers (Certificate of Pharmaceutical Product: CPP or GMP Certificate is required)

Drug Registration and Approval Process



GMP Inspection System

- Domestic
- Overseas

Overseas

GMP Clearance of Overseas Pharmaceutical Manufacturers

- -PIC/S and ASEAN Listed Inspection Service
- -Certified by PIC/S and ASEAN Listed Inspection Service
- -Non-PIC/S

Quality, Safety and GMP in radiopharmaceutical practice in Thailand

Guidance documents on quality, safety and GMP in radiopharmacy is Under Revision

Current status of radiopharmacy GMP compliance comply with PIC/S guideline

Guide to Good Practices for preparation of medicinal products in Healthcare Establishment (follow PIC/S PE010-4) IAEA and WHO as complementary for : small scale production of radiopharmaceuticals and in-house production of PET and therapeutic RPs in Hospitals.

Quality control of RPs is considered according to International Pharmacopeia: Radiopharmaceutical monographs updating in association with WHO. Results are controlled in CTDs

fppt.com

Future Plan

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Future Plan

Developing Guidance on Registration of specific to Radiopharmaceutical products

Developing on Guide to Good Practices for preparation of medicinal products in Healthcare Establishment (follow PIC/S PE010-4)

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Acknowledgements

- Dr. Suchart Chongprasert,

Director, Bureau of Drug Control, Thai FDA

- Dr. Putthiporn Charoenphun,

Division of Nuclear Medicine, Faculty of Medicine, Ramathibodi Hospital, Mahidol University

- Supattra Pongsri,

Pre-Marketing Control Division Thai FDA

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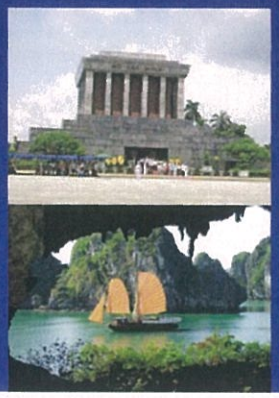
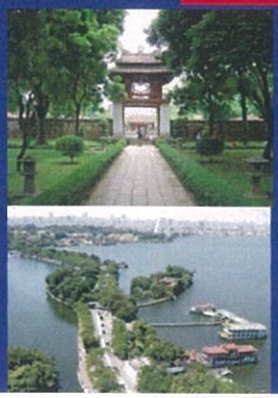
APPLICATION OF NUCLEAR MEDICINE IN DIAGNOSIS AND TREATMENT OF CANCER AND OTHER DISEASES IN VIETNAM

MAI TRONG KHOA, Prof., PhD., MD.
The Nuclear Medicine and Oncology Center, Bach Mai Hospital
The Nuclear Medicine Department, Hanoi Medical University
Hanoi-Vietnam

VIET NAM

Equipments of Nuclear Medicine

Equipment	Number
SPECT	25
SPECT/CT	15
PET/CT	12
Radioactive seed implant system	1
Dose calibrator	39
I-131 concentrator	31
Osteoporosis meter	19
RIA, IRMA system	5
Cyclotron	5
REACTOR	1

Human resources of Nuclear Medicine

Human resources	Number
Nuclear Medicine physician	163
Medical physicist	45
Radiopharmacist	29
Nuclear Medicine technician	101
Nuclear Medicine nurse	186

NUCLEAR MEDICINE IN VIETNAM

❖ **In Vietnam:** - Department (center) of N.M.
- Department (center) of Oncology
- *Combination:* NM and Oncology of Department (Center)

❖ **Human resource capacity:**

- NM Physicians : 163
- Medical physicists: 45
- Radiopharmacitical Pharmacist: 29
- NM Physicians and Oncologists (2 certificates)

Production and supply of radiopharmaceuticals and marked compounds in Vietnam

❖ *Production of Radiopharmaceutical:*

✓ There is only one nuclear reactor in Da Lat that produces some radiopharmaceuticals: I-131, P-32, Tc-99m ... and some marked compounds.

✓ Production capacity is unable to meet the needs of nuclear medicine and oncology facilities throughout the country.

✓ Radioactive isotopes, marked compounds produced by the Da Lat Nuclear Research Institute have expired visa of the Ministry of Health of Vietnam. They are applying for re-issuance.

❖ *The import of radiopharmaceuticals:*

✓ Many radiopharmaceuticals marked compounds must be imported from abroad to meet the needs of diagnosis and treatment in hospitals.

✓ There is only one company eligible to be licensed by the Ministry of Health to import, distribute and transport radiopharmaceuticals. NM and Oncology facilities are facing many difficulties and always lack of radiopharmaceuticals for diagnosis and treatment.

✓ Some hospitals are importing Radiopharmaceuticals from companies that do not have permission from the Ministry of Health

❖ *The operation of Cyclotron:*

✓ Vietnam currently has 5 cyclotrons (03 cyclotrons are in operation).

✓ The amount of FDG is insufficient for the operation of 12 PET / CT machines.

NUCLEAR MEDICINE IN VIETNAM: ONCOLOGY, CARDIOLOGY, NEUROLOGY, ENDOCRINOLOGY…

- >90% NM techniques are using in oncology
- < 10% in Cardiology and Neurology, Endocrinology…

7

BASIC INFORMATION

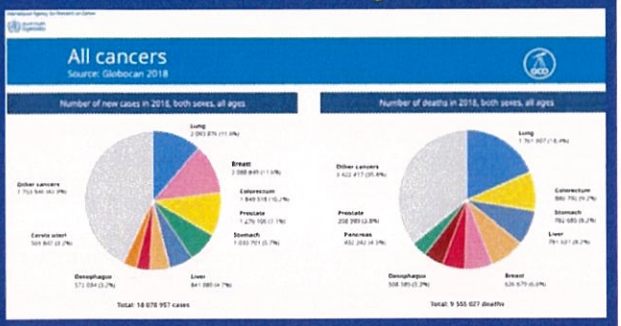
1. Population: 94 millions
2. Cancer incidence statistics:

People newly diagnosed with cancer / year	165,000
Age-standardised rate, incidence per 100,000 people/year	140.4
Risk of getting cancer before age 75	14.5%
People dying from cancer /year	115.000

Data from IARC GLOBOCAN (2018)

8

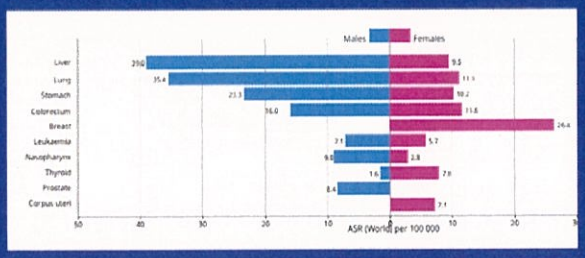
Number of new case and number of deaths in 2018, both sexs, all ages



Globocan 2018: 18 millions of new case and > 9,5 million deaths

GLOBOCAN 2018

Number of new case and number of deaths in 2018, both sexs, all ages (In Vietnam)

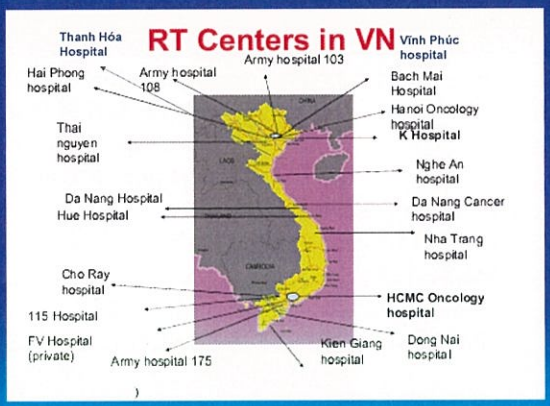


In Vietnam (2018) each year there are 165,000 new cases and 115,000 deaths due to cancer

GLOBOCAN 2018

Application of Radiation in Medicine

- Applications of Radiation in Medicine: Radiology, Nuclear Medicine and Radiation Oncology
- Recently, there are many new radiation techniques being used in diagnosis and treatment of diseases, especially in oncology field.
- The rising trend of morbidity and mortality rate of cancers was observed in Vietnam. The number of Radiology, nuclear medicine, oncology Department/ Center are likely to increase in order to meet the needs of diagnostic and treatment for patients
- Many new technologies have been updated and applied in Vietnam
- Support of the Government, Ministries and Agencies



Nuclear Medicine In Bach Mai Hospital

13

EQUIPMENTS IN BACH MAI HOSPITAL (Combination: NM and Oncology Center)

- 1 PET/CT Simulation, 2 SPECT, 2 CT Simulation
- 1 Seed Implant Therapy System with I-125 for Prostate Cancer
- Selective Internal radiation Therapy- SIRT (with Y-90) for liver cancer
- 1 LINAC
- 1 Brachytherapy
- 1 Rotating Gamma knife, MRI Simulation

14

Nuclear Medicine (Examinations)

Examinations *(Bach Mai Hospital)*		
Numbers of Patients/Day (/Month, /Year)	SPECT	PET/CT
Numbers of Patients/Day	25-30 (7 days/week)	10 - 15
Numbers of Patients/Month	800	200-220
Numbers of Patients/year	8000	2200

No. of applied nuclear medicine procedures (2016)

Year: 2016	Gamma (SPECT)	PET/CT	Therapy	Total
Oncology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital and Cho ray Hospital)*	20.765	12.756 *(10.785 in Bach Mai Hosp.)*	7.270	40.791
Cardiology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital, Army Hospital-108 and Cho ray Hospital)*	1.214	46	N/A	1.260
Neurology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital, Army Hospital-108 and Cho ray Hospital)*	167	287	N/A	454
Total	22.146	13.089	7270	42.505

No. of applied nuclear medicine procedures (2017)

Year: 2017	Gamma (SPECT)	PET	Therapy	Total
Oncology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital and Cho ray Hospital)*	143.347	11.985 *(10.112 in Bach Mai Hosp.)*	9.604	164.936
Cardiology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital, Army Hospital-108 and Cho ray Hospital)*	1431	54	N/A	1.485
Neurology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital, Army Hospital-108 and Cho ray Hospital)*	173	387	N/A	560
Total	144.951	12.426	9.604	166.981

No. of applied nuclear medicine procedures (2018)

Year: 2018	Gamma (SPECT)	PET	Therapy	Total
Oncology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital and Cho ray Hospital)*	147.432	12.777 *(11.322 in Bach Mai Hosp.)*	7.782	167.991
Cardiology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital, Army Hospital-108 and Cho ray Hospital)*	1.332	52	N/A	1.384
Neurology No. of applied nuclear medicine procedures/ treated or diagnosed patients *(Bach Mai Hospital, Army Hospital-108 and Cho ray Hospital)*	195	392	N/A	587
Total	148.959	13.221	7.782	169.962

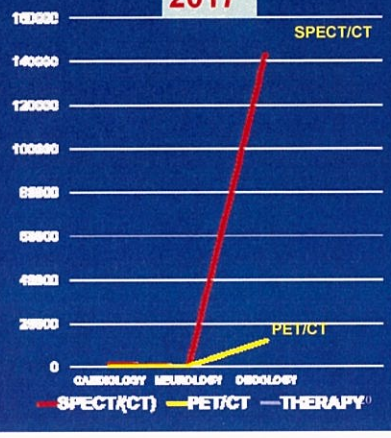
2016

No. of applied nuclear medicine procedures (2016)

19

2017

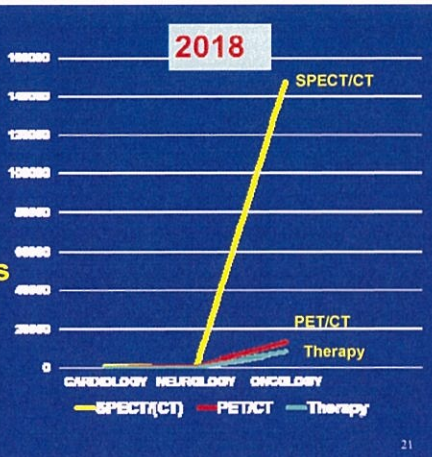
No. of applied nuclear medicine procedures (2017)



20

2018

No. of applied nuclear medicine procedures (2018)



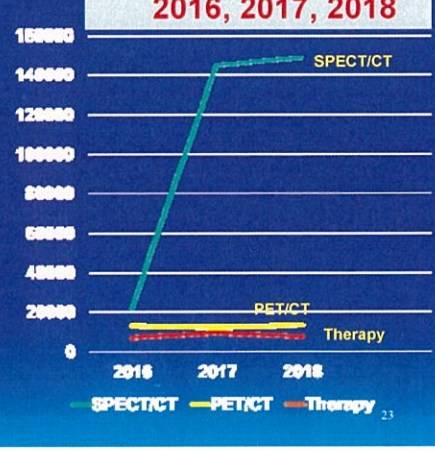
21

No. of applied nuclear medicine procedures (2016, 2017, 2018)

22

No. of applied nuclear medicine procedures (2016, 2017, 2018)

2016, 2017, 2018

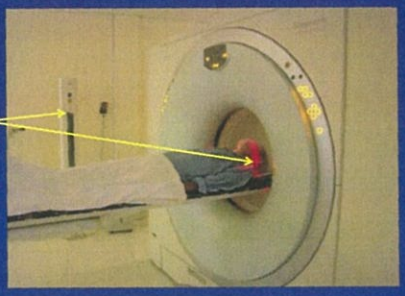


23

PET/CT simulation for radiotherapy planning in Vietnam

PET/CT SIMULATION

- Localization by 3D laser system (X-Y-Z)
- PET/CT scan

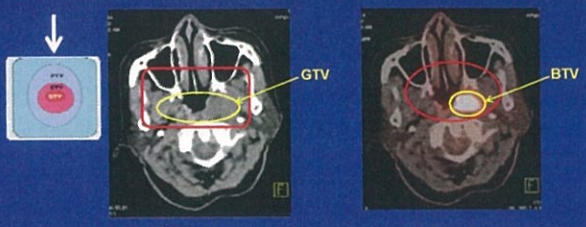


The Nuclear Medicine and Oncology Center
Bach Mai Hospital

RADIOTHERAPY PLANNING

CT simulation to define radiation volumes
GTV – Gross tumor volume CT or MRI
CTV – Clinical target volume
PTV – Planing target volume .

PET/CT simulation:
BTV biologic target volume – biological tumor volume – including metabolic information of the tumor – early and accurate.



CT image PET/CT image

PET / CT SIMULATION AND IMRT RADIATION THERAPY PLANNING IN THE NUCLEAR MEDICNE AND ONCOLOGY CENTER, BACH MAI HOSPITAL

(Science Technology Innovations in medicine, 2011)

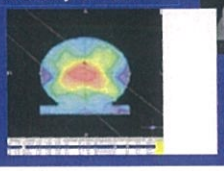
1. Patient preparation

2. PET/CT simulation

3. Radiotherapy planning base on PET/CT simulation

5. Treatment

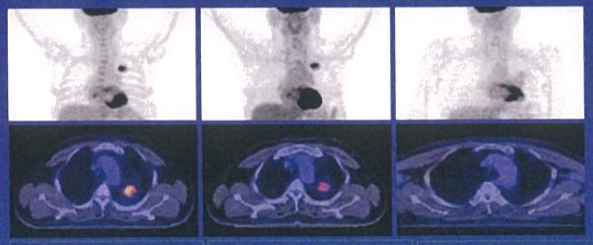
4. Quality control



Award from the Ministry of Health to the Nuclear Medicine and Oncology center for the application of PET/CT simulation for Intensity Modulated Radiation in cancer treatment

BỘ TRƯỞNG BỘ Y TẾ
TẶNG
BẰNG KHEN
ỨNG DỤNG KỸ THUẬT PET/CP MÔ PHỎNG XẠ TRỊ ĐIỀU
BIẾN LIỀU TRONG ĐIỀU TRỊ UNG THƯ
CỦA TRUNG TÂM Y HỌC HẠT NHÂN VÀ UNG BƯỚU, BỆNH VIỆN BẠCH MAI

Case study: Nguyen B. T., male, 59 years old, Lung cancer T2N0Mo, Squamous cell carcinoma. Chemo + IMRT: 66Gy, 6 beams with PET/CT simulation

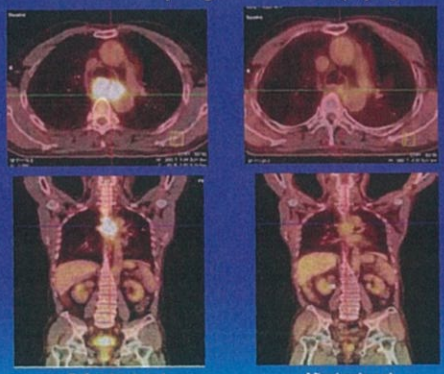


- Prolong dry cough
- Lung tumor before treatment: 2×3 cm SUV=6,89

- Lung tumor after 3 cycles of chemotherapy: SUV=3,24

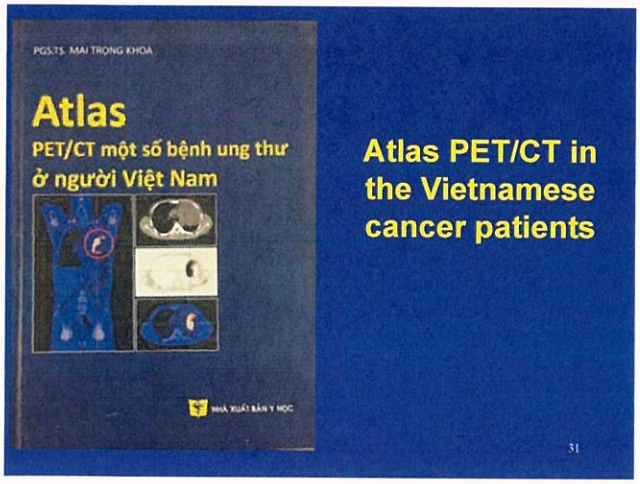
After 6 cycles of chemo + radiation: - No cough
- Complete response
- Low radiation complication. Good QoL

Male, 45 ys
Middle eosophageal cancer, $T_4N_0M_0$



Before treatment
Tumor 5x7,2cm, max SUV=11,86

After treatment.
Tumor 2,9x1,2cm, max SUV=3,10



Atlas PET/CT in the Vietnamese cancer patients

31

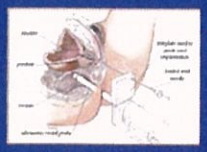
PERMANENT RADIOACTIVE I-125 SEEDS IMPLANT

Seed Implant Therapy for Prostate Cancer

PERMANENT RADIOACTIVE SEEDS IMPLANT

Small size I-125 seeds

I-125 seeds in the applicator



I-125 seed implant into prostate under the ultrasoul guidance

I-125 seeds are implanted directly into the prostate tumor, destroying tumors while less affecting the surrounding healthy organs such as bladder, rectum, diminishing complications for the patient, physiologic function remained.

PERMANENT RADIOACTIVE I-125 SEEDS IMPLANT AT BACH MAI HOSPITAL

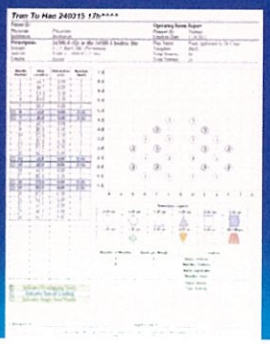
In Vietnam, the permanent radioactive I-125 seed implant was first implemented in the Nuclear Medicine and Oncology center of Bach Mai hospital since April 2015

- **> 10 prostate cancer patients have been treated**
- **Effective: 100% symptoms reduction, PSA become normal, improvement of life quality**
- **Safety: No serious complications**

Radioactive seed implant: Prostate cancer Bach Mai Hospital.

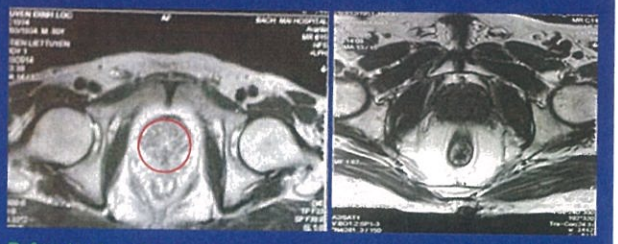
CASE STUDY

- Permanent radioactive seed implant: 24 needle, 64 seeds, total I-125 dose: 145 Gy



Case study 1

Tran Tu H., male, 63 years old, the first prostate cancer patient in Vietnam treated by permanent radioactive I-125 seed implant

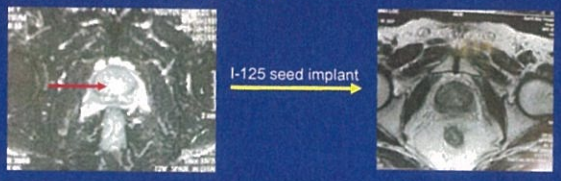


Before treatment:
frequency urinary, urinary retention
PSA: 28.5ng/ml.
MRI: prostate tumor less invasive seminal vesicle

After treatment:
Normal urinary
PSA: 0.91 ng/ml.
MRI: prostate tumor disappeared

Case study 2

NGUYEN D. L ., male, 80 years old patient, difficult urinary, urine leak
MRI: prostate tumor 12 x 15 mm, less invasive seminal vesicle
Pathology: adenocarcinoma, Gleason score: 7
→ Diagnosis: **Prostate cancer T2N0M0**



Before treatment:
Tumor size 12 x 15 mm, Difficult urinary, PSA: 24 ng/ml.

12 months after treatment:
Prostate tumor disappeared PSA 0.26 ng/ml; Normal urinary

Selective internal radiation therapy (SIRT) with Y-90 microsphere

For primary and secondary liver cancer

Selective Internal Radiation Therapy: SIRT

Place radioactive Y-90 microspheres into the liver tumor arteries. The microspheres lead to embolization of the feeding arteries and destroy the tumor cells by beta energy of Y-90.

Radioactive seed: ^{90}Y
Size: 35µm $T_{1/2}$: 64.1h;
Beta radiation energy: 0.93 Mev
Wavelength: 2,5-11mm

EFFECTIVE AND SAFETY

Selective Internal Radiation Therapy: SIRT

PROTOCOL

Phase 1

DSA scan

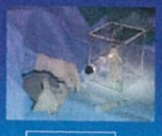
Inject Tc-99m-MAA to artery feeding liver tumor

Lung Shunting

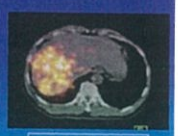
Y-90 dose calculation

Phase 2

DSA scan

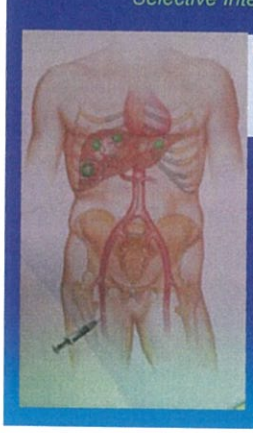


Inject ^{90}Y

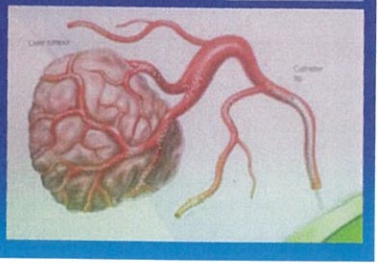


Post PET/CT

Selective Internal radiation Therapy: SIRT

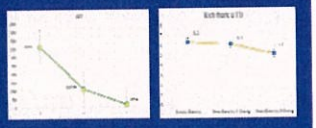


Radioactive microsphere ^{90}Y:
Size 35µm,
T1/2: 64,1h;
Eß=0,93 Mev;
Tissue range: 2,5-11mm.



Treatment outcome of SIRT at Bach Mai hospital

- Bach Mai Hospital is the first place in Vietnam to implement this technique
- 57 patients were treated with good outcome, high efficiency and safety.



Response status	After 1 month		After 3 months	
	N	Rate (%)	N	Rate (%)
Completed response	2	4.87	8	21.6
Partial response	39	95.13	29	78.4

BCLC A: 22.7 ± 1.2 month
BCLC B: 19.7 ± 1.0 month
BCLC C: 10.9 ± 0.9 month

Case Study (Primary HCC)

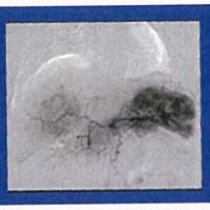
Nguyen Van C; male, 68y

•**Diagnosis:** Primary hepatocellular carcinoma (HCC) stage B/ HBV (+), hypertension.

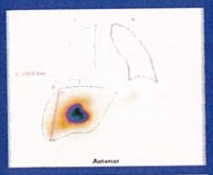
•**Treatment:**

- HBV: Baraclude 0,5 mg, 1 tablet/day
- Hypertension: Coversyl 5 mg, 1 tablet/day
- Liver tumor: SIRT Y- 90 microsphere, dose 1,06 GBq

Pretreatment CT



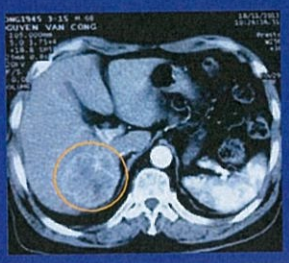
DSA liver tumor arteries



SPECT Tc99m-MAA

Y-90 PET/CT

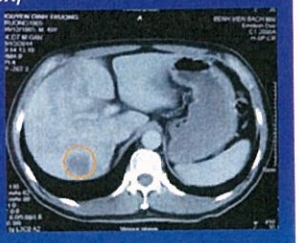
Efficacy post Y-90 (Primary HCC)



Before treatment	After 6 months
• Fatigue, pain near the right shoulder blade, anorexia, weight loss • Liver tumor: 62x58 mm • Intensive contrast enhancement • AFP: 29,36 ng/ml	• Normal symptom, gain 2kg • Decrease in size of tumor: 30x20 mm • No contrast enhancement • AFP: 2,4 ng/ml

CASE STUDY (Metastatic liver tumor)

N. Đ. T, male 59y. Adenocarcinoma of Sigma Colon Cancer with liver metastases (TxN0M1), KRASwt, treated by SIRT with Y-90 microsphere + Chemotherapy (FOLFOX 4 + ERBITUX)



Before treatment:
Tumor 7,0X8,6 cm
CEA > 1000ng/ml

After 6 months:
Tumor 3,0 X 3,5cm
CEA: 23,7ng/ml

RADIATION THERAPY AND PET/CT SIMULATION

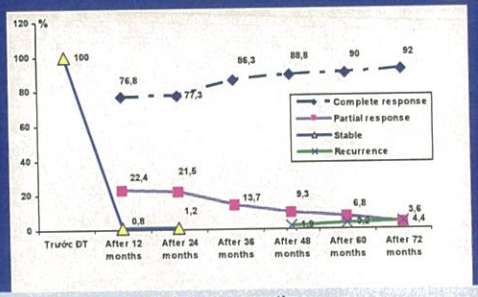
Radiosurgery:

ROTATING GAMMA KNIFE AT BACH MAI HOSPITAL

49

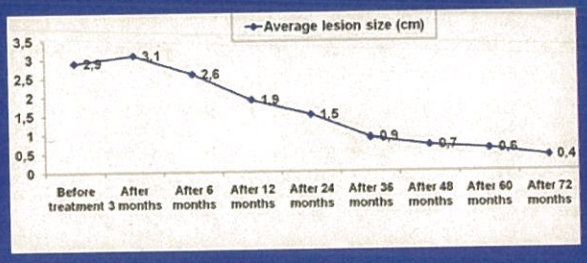
6000 PATIENTS WITH BRAIN TUMORS AND INTRACRANIAL DISEASES TREATED WITH ROTATING GAMMA KNIFE AT BACH MAI HOSPITAL

Proportion of patients with the improvement in clinical symptoms after radiosurgery



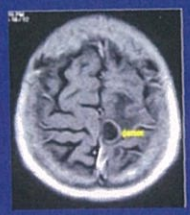
Clinical symptoms gradually improve over time.
Symptoms have disappeared among 76.8% of patients after 1; 77.3% after 2 years; 86.3% after 3 years; 88.8% after 4 years; 90.0% after 5 years; 92% after 6 years. The recurrence rate after 4 years is 1.9%; after the fifth year, it is 3.2%; 4.4% after the sixth year.

Changes in the size of lesions after radiosurgery

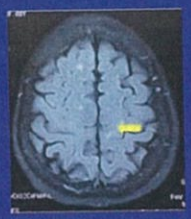


The average size of lesions before treatment was 2.9 ± 1.5cm.
After treatment: the size of lesion is controlled after 6 months,
After 6 years, the lesion size was reduced to 0.4 ± 0.7cm.

Case study: Brain metastases



Before Tx: weak at right leg, brain lesion 1,9x2cm with edema

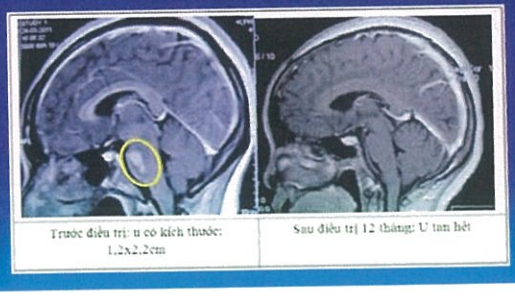


After Tx: good clinical, complete response

Tran T. Đ., female, 68 years old; weak at right leg; Diagnosis: Lung cancer with brain and bone metastases T3N0M1. Adenocarcinoma, EGFR (+)→ treated with RGK 24 Gy, Chemo 6 cycles + TKI

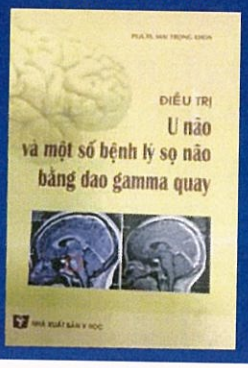
Case study – Brainstem Glioma

Nhu Thi N. Q., 14 y, headache, ptosis, esotropia. MRI: anaplastic astrocytoma in the pons with size: 2,2x1,2cm → RGK 14Gy. After 12 months: complete response, improved headache, no esotropia.



Trước điều trị: u có kích thước 1,2x2,2cm | Sau điều trị 12 tháng: U tan hết

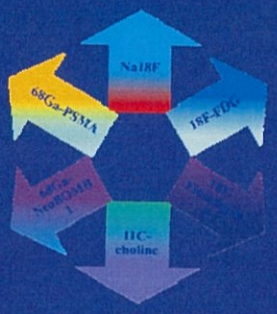
Radiosurgery: Treatment of patients with brain tumors and intracranial diseases by Rotating Gamma Knife



APPLICATION OF ADVANCED RADIATION TECHNOLOGY IN FUTURE OF VIETNAM

NEW RADIOPHARMACEUTICALS FOR PET

TRACERS FOR HYBRID IMAGING



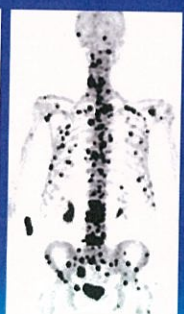
18F-FLUORIDE (18F-NaF)

	PLANAR	SPECT	18F-NaF	18F-NaF PET-CT
Sensitivity	70%	92%	100%	100%
Specificity	57%	82%	62%	100%

Even-Sapir E, Metser U, Mishani E, et al: The detection of bone metastases in patients with high-risk prostate cancer: 99mTc-MDP planar bone scintigraphy, single- and multi-field-of-view SPECT, 18F-fluoride PET, and 18F-fluoride PET/CT. J Nucl Med 47:287-297, 2006

18F-FCH (fluoromethylcholine) and 18F-NaF: Bone metastases in the prostate cancer:

18F-FCH PET



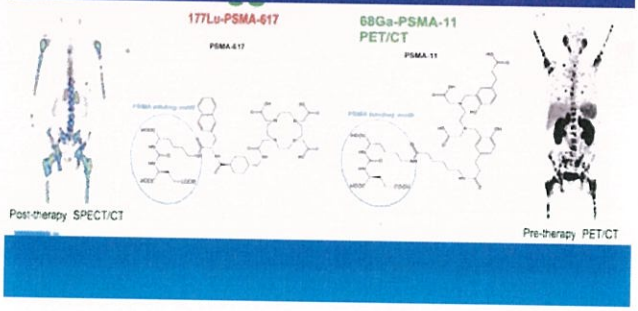
18F-NaF PET

Male patient, 73 years old, Diagnosed: Prostate cancer. FCH PET and 18F-NaF PET after 6 months of treatment showed multifocal bone metastases (PSA increased to 62 ng / ml)

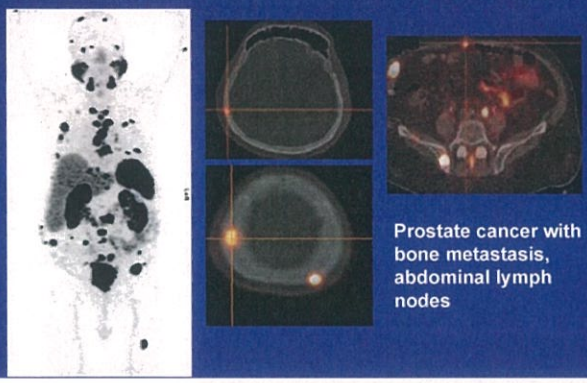
Beheshti M, Prostate Cancer: Role of SPECT and PET in Imaging Bone Metastases Semin Nucl Med 39:396-407 © 2009 Elsevier Inc.

THERANOSTICS

- TARGETED THERAPEUTIC + DIAGNOSTIC COMPANION



68Ga-PSMA
(Prostate – Specific Membrane Antigen)

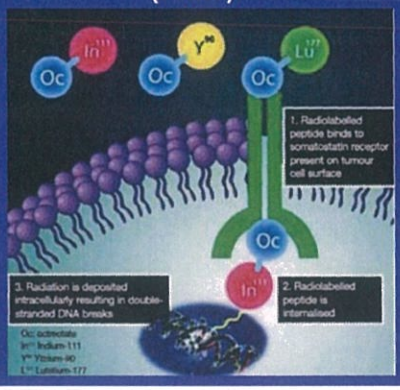


Prostate cancer with bone metastasis, abdominal lymph nodes

Peptide Receptor Radionuclide Therapy (PRRT)

- A method of using radioactive isotopes attached to peptides, this complex passes through the peptide receptor on the surface of the tumor cell into the tumor cell and destroys it.
- The peptides like Octreotide, DOTATOC, DOTATATE and DOTANOC have high affinity for SSTR2.

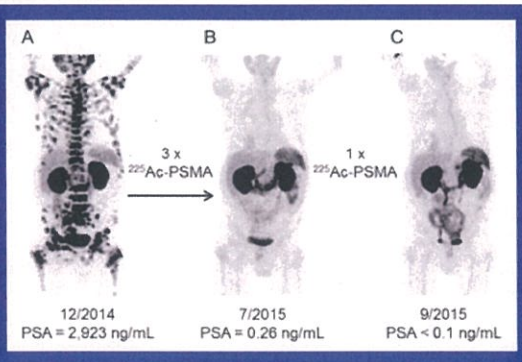
Peptide Receptor Radionuclide Therapy (PRRT)



ALPHA-EMITTERS RADIOPHARMACEUTICALS IN TARGETED ALPHA THERAPY (TAT)

- Ra-223: treatment of bone metastatic cancer
- Y-90-octreotide: treatment of neuroblastoma
- Lu-177-octreotide: treatment of neuroblastoma
- Bi-213-cDTPA: melanoma treatment
- ^{225}Ac-PSMA-617: treatment of prostate cancer

...



^{225}Ac-PSMA-617 (target treatment with alpha emitters radiopharmaceuticals) for patients with metastatic prostate cancer

Kratochwil C. et al. JNM July 2016

THE NUCLEAR MEDICINE AND ONCOLOGY CENTER

Mr. Yukiya Amano - Director General of the International Atomic Energy Agency (IAEA) visited The Nuclear Medicine and Oncology Center – Bach Mai Hospital, January 2014

President of Viet Nam awarded the Ho Chi Minh prize on Science and Technology to Professor Mai Trong Khoa in 2017, for the project in which he was the leader, entitled: ***"Applications of modern techniques of ionizing radiation in the diagnosis and treatment of cancer and some other diseases".***

This is the best and excellent award for the Science and Technology in Vietnam

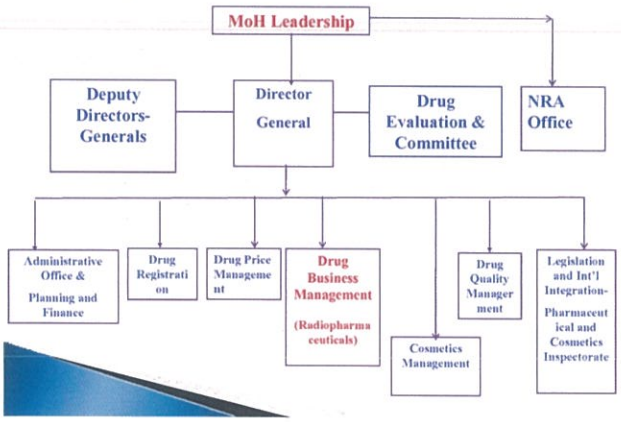
MINISTRY OF HEALTH
DRUG ADMINISTRATION OF VIETNAM

Vietnam's Regulations on Radiopharmaceuticals

Mrs. Nguyen Dieu Ha,
Deputy head Pharmaceutical Business Control Division,
Drug Administration of Vietnam.

Part I:
Overview of Drug Administration of Vietnam's organizational structure, functions

Drug Administration of Viet nam



Scope of management:

1. Medicines for human use which include:
   - Modern medicines (including: radiopharmaceuticals).
   - Traditional medicines, herbal medicines.
   - Medicinal raw materials
   - Vaccines
   - Biologics (except biologics in vitro).
2. Cosmetics.

Licensing activities

1. Licensing, withdraw MA of medicines; Issue, withdraw FSC, CPP.
2. Issue, withdraw medicine import-export licences.
3. Issues, withdraw pharmaceutical practice certificates; business eligibility certificates for activities related to drug production, storage, distribution, GLP services; foreign pharmaceutical companies licensing.
4. Issues, withdraw certificates of GMP, GSP, GLP.
5. Issue, withdraw cGMP certificates; cosmetic notifications, FSC, cosmetic import licences.
6. Inspection and enforcement.

Part II:
Vietnam's Regulations on Radiopharmaceuticals

Content

1. Law on Pharmacy 2016
   2/ Degree 54/2017/NĐ-CP dated 08/5/2017
   3/ Degree 155/2018/NĐ-CP dated 12/11/2018
   4/ Circular 20/TT-BYT
2. Proposals and Recommendations

Law on Pharmacy 2016

- *Concepts:*

Radiopharmaceutical (Radioactive Drug): Drug that contains radionuclides used for diagnosis, treatment of diseases in humans or medical-biological research, including:

Radioactive isotopes or

Radioactive isotopes combined with tracers.

Law on Pharmacy 2016
PHARMACY BUSINESS ESTABLISHMENT

1. **Manufacturer**
2. **Importer- Exporter**
3. **Whole saler**

.....

Law on Pharmacy 2016

CONDITIONS FOR TRADING IN RADIOPHARMACEUTICAL
(Article 34)

Any establishment trading in radiopharmaceuticals must be approved in writing by a pharmacy Authority (Certificate of Satisfaction of Conditions for trading in pharmaceuticals)

The Government shall provide for:

1. Procedures for granting business permission
2. Measures for protecting controlled drugs/medicinal ingredients from loss

CONDITIONS FOR TRADING IN RADIOPHARMACEUTICAL

Establishment trading in radiopharmaceuticals must fulfil:

1. Every condition specified in Article 33 of Pharmacy Law corresponding to the conditions for each type of establishment:
- Material/ technical facilities and personnel resources;
- Pharmacy practice certificates of the person in charge of pharmacy expertise and the persons holding the specified positions
2. Security Measures **(Articles 43- 48)**: Material/ technical facilities ; Personnel resources; Mechanisms for Drug Delivery, Transportation, Buying and Selling, Report, Disposal
3. Satisfy the conditions specified in the Law on Atomic Energy and relevant legislative documents

Radiopharmaceutical Manufacturers

Material/ Technical Facilities:

1. GMP manufacturing plant
2. License to conduct radiation work
3. A separated warehouse for storage of radiopharmaceuticals or a separated area meeting GSP requirement
4. A system of recording dossiers and books to monitor and manage, in accordance with MOH regulations
5. Camera equipped

Personnel Resources:

1. Storekeeper: intermediate degree in pharmacy/bachelor of radiation chemistry/ bachelor specialized in radiation medicine or nuclear medicine;
2. The person in charge of overseeing the process of research, production, analysis and testing must be a bachelor of radioactive chemistry, a bachelor of radiation medicine or a nuclear medicine or pharmacy.

Radiopharmaceutical Importer/ Exporter and Wholesaler

1. GSP/GDP warehouse
2. A system of recording dossiers and books to monitor and manage, in accordance with MOH regulations
3. Meet all requirements and regulations on Atomic Energy and Nuclear

Import/ Export of Radiopharmaceuticals

- ***MOH to grant Import/ Export licenses for radiopharmaceuticals (with or without Drug Registration Number)*** to enterprises that have the functionality of drug import/ export (procedures specified in Decree 54/NĐ-CP/2017) *The license is valid for 1 year*
- ***Department of Radiation Safety - Ministry of Science and Technology*** manages and grants licenses for Import, Production, Transport; licenses for medical examination and treatment facilities and individuals with activities related to radiopharmaceutical in accordance with the Law on Atomic energy

The license is valid for 1 year

Radioactive drugs are only used for people when: - Have a paper of registration for circulation in Vietnam (registration number) I

* *Radiopharmaceuticals may only be used for people when*

- *Marketing approval (Drug Registration No.) is granted*
- *Drug Import license is granted (if no Drug Registration No. granted yet)*
- *Public health establishments: buying radio-pharmaceuticals in the form of Drug Bidding*

The granting of Marketing Approval (Drug Registration No) for Radiopharmaceuticals in VN

- Domestics radiopharmaceuticals, tracers: 11 (Dalat Institute of Nuclear Medicine since 2010).
- Imported drugs: 01 radiopharmaceutical.
- Several companies are completing their dossiers to apply for drug marketing approval in Vietnam

Certificate for Satisfaction of Conditions for doing pharmaceutical business (CSC):

DAV has granted 04 business establishments to do import/ export, wholesale of radiopharmaceuticals .

Proposals and Recommendations

The management of radiopharmaceuticals should be strengthened to ensure drug quality, safe and rational use for patients

Proposals and Recommendations

1. Strengthening quality control for both locally produced radiopharmaceuticals and imported radiopharmaceuticals

2. Enhancing information exchange and training between state management agencies on health and state management agencies on radiation safety

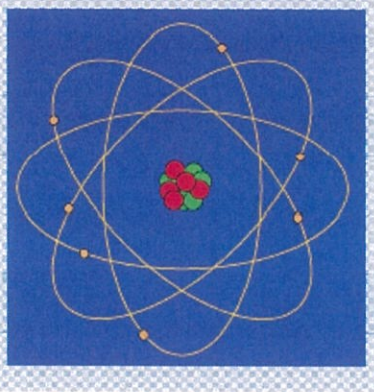
3. Need support from International Atomic Energy Agency (IAEA) and regulators of radiopharmaceuticals of countries in the world, particularly countries in our region

THANK YOU
FOR YOUR ATTENTION

A LONG JOURNEY OF NUCLEAR MEDICINE IN MYANMAR

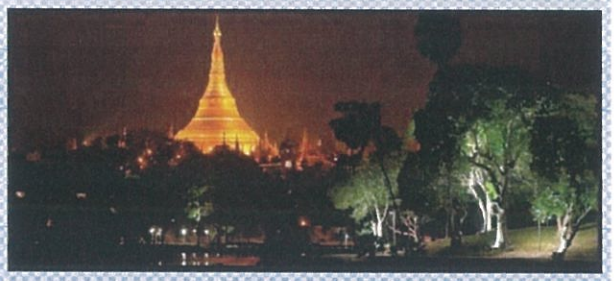
Prof. KYIN MYINT
MBBS, M.Sc. (Nuclear Medicine), FANMB
President
Myanmar Nuclear Medicine Society (MNMS)

ATOM FOR PEACE



THE REPUBLIC OF THE UNION OF MYANMAR

SHWE DAGON PAGODA



THE REPUBLIC OF UNION OF MYANMAR

- Area: 676,552 sq km
- Population: About 60 Millions
- M : F = 41 : 59
- Capital: NAY PYI TAW
- Country Independence on 4th January 1948

THE BEGINNING

- Department of Radioisotopes founded at Yangon General Hospital in 1963, after the visit of Dr. E. H. Belcher, the then head of Divisions of Life Sciences, IAEA
- The first IAEA expert service in JUNE 1965, Dr R. Hoschl from Czechoslovakia and co-founder Dr.SOE MYINT, the then head of the Unit
- Thereafter, a number of expert services are provided by IAEA under TC project till now.
- IAEA has played a pivotal role in the development and sustainability of Nuclear Medicine services in MYANMAR.

MILESTONES OF NUCLEAR MEDICINE IN MYANMAR

- 1966 – Rectilinear scanner (IAEA project BUR/6/04)
- 1968 – Three Probes Scintillation detector (IAEA BUR/6/04)
- 1974 – Well counter with automatic sample changer, Printer, and Liquid Scintillation counter (IAEA BUR/6/05)
- 1975 – OHIO Nuclear Gamma Camera donated by Japanese Government
- 1987 – Fully equipped Nuclear Medicine Unit with HITACHI Gamma Camera at JICA hospital, Yangon (JICA Aids)
- 1998 – Department of Nuclear Medicine, Mandalay General Hospital, Mandalay provides services with single head SPECT Gamma Camera (SIEMENS E. CAM), by the Government of MYANMAR

MILESTONES OF NUCLEAR MEDICINE IN MYANMAR

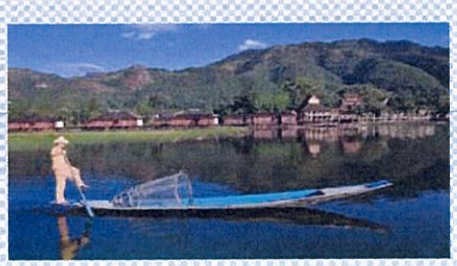
- 2003 – New Department launched at North Okkalapa Teaching Hospital, YANGON
- 2003 – The first dual head SPECT gamma camera (SIEMENS E. CAM) was installed at the Department of Nuclear Medicine, YGH by the Government of MYANMAR
- 2009 – New Department launched at 1000 bedded specialist hospital in NAY PYI TAW with Intermedical dual head SPECT Gamma Camera, by the Government of MYANMAR

NUCLEAR MEDICINE SERVICES IN MYANMAR

- Department of Nuclear Medicine, Yangon General Hospital, YANGON
- Department of Nuclear Medicine, North Okkalapa General Hospital, YANGON
- Department of Nuclear Medicine, Mandalay General Hospital, MANDALAY
- Department of Nuclear Medicine, Naypyitaw 1000 bedded General Hospital, NAY PYI TAW

DEPARTMENTS OF NUCLEAR MEDICINE

Famous Inle lake



YANGON GENERAL HOSPITAL (Since 1899)

Department of Nuclear Medicine (Yangon General Hospital)

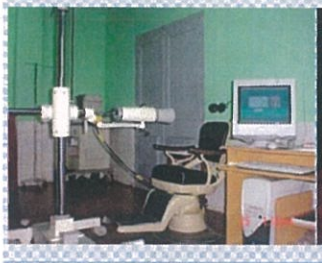
EQUIPMENTS

Rectilinear Scanner 1979

Pho /Gamma Camera 1975

Gamma muvek MB 9100 Gamma camera 1985

EQUIPMENTS

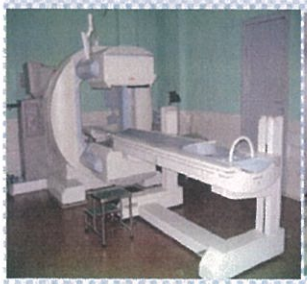


Thyroid Probe

Gamma Well Counter

HOT LAB (Fume Hoods for ^{131}I solution & ^{99m}Tc generator)

Nuclear medicine department yangon general hospital



SPECT GAMMA CAMERA (2003)

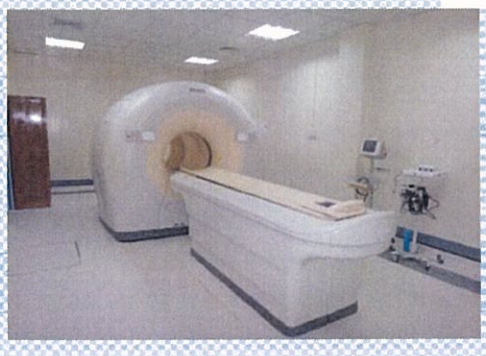
SPECT-CT CAMERA (2013)

Perkin elmer gamma counter 2014

PET-CT & CYCLOTRON CeNTER

2016

PHILIPS PET- CT
(GEMINI, TOF, 16 slices) 2015



CYCLOTRON - YGH

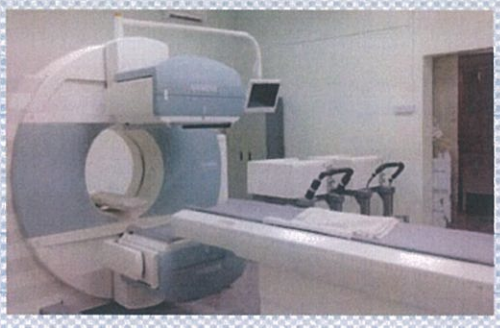
COMMERCER HOT CELL WITH SYNTHERA

PET-CT CONTROL ROOM

Adenocarcinoma of stomach

Single Head SPECT GAMMA CAMERA (Siemens E. Cam) 2000

SPECT/CT, SYMBIA t6 (Nuclear Medicine, MGH) 2014



Nay pyi taw 1000 Bedded General Hospital

Dual Head Gamma Camera (Nay pyi taw) 2010

SPECT/CT, Discovery-670 (Nuclear Medicine, Nay pyi taw) 2014

North okkalapa general hospital YANGON

Siemens spect–ct (symbia t6) 2015

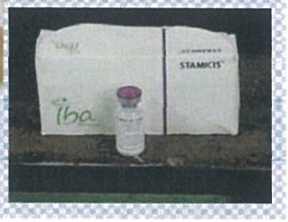
Staffs in Nuclear Medicine departments of Myanmar

	YGH	MDY	NPT	NOGH
Physicians	10+	1	1	2
Physicist	3	1	Nil	Nil
Technologists In-vivo	8+	4	1	1
Radio-pharmacist	2	Nil	Nil	Nil
Technologists In-vitro	2	2	Nil	Nil

^{131}I & ^{99m}Tc Generator from ANSTO (The Past)

^{131}I & ^{99m}Tc Generator (The Present)

Radiopharmaceuticals (these days)



Nuclear medicine procedures

- SPECT-CT: General Nuclear Medicine Imaging (Thyroid scan, Bone scan, Renal scan, Myocardial perfusion imaging, Liver scan, Hepato-biliary imaging, Parathyroid scan, etc...)
- In-vitro studies (Radioimmunoassay) of thyroid related hormones
- PET-CT: Mainly for Oncology (^{18}F-FDG)
- Radioactive Iodine (^{131}I solution) therapy for thyrotoxicosis and differentiated thyroid carcinoma

Prof. M. Dondi's visit to Myanmar JUNE, 2012

Prof. Ajit Padhy & Dr. Felix X. Sundram, November, 2012

Beautiful Bagan

Academic programs

- Acdemic Degree:
  - Diploma Med. Sc. (Nuclear Medicine) - One year; started in 1999 and ended in 2007
  - M. Med. Sc. (Nuclear Medicine) - two years from 2007 -2016
  - M. Med. Sc. (Nuclear Medicine) - Three years from 2017
- Training at the Yangon General Hospital, affiliated to University of Medicine 1, Yangon
- Entry by competition (Entrance examination) after 2 years experience of clinical practice in Government Hospitals, NOT for private sector

Myanmar nuclear medicine Society (MnmS)

- Myanmar Society of Nuclear Medicine (MSNM)
  - Formed in 2014
  - President: Prof. KYIN MYINT
  - Member: 45 (including physicists & technologists)
  - Member of WFNMB, AOFNMB, ARCCNM & WARMTH
  - Participated in local and international allied Societies' activities
- Successfully done IAEA QUANUM audit at Nuclear Medicine Department, YGH in September 2016

MYANMAR PERSPECTIVE

- No Health insurance system in MYANMAR, as a developing country
- No reimbursement
- Government's SUPPORT plays a pivotal role in Infrastructure as well as the Effective use of radiopharmaceuticals in the diagnosis and management of human diseases, but limited budget.

Ngapali Beach

First IAEA-RTC in Yangon, dec 2012 (RAS6063)

Gala dinner at karaweik (IAEA-RAS6063)

IAEA-RAS 6076-003 in Yangon, Myanmar July, 2016

RAS6076-003 in Yangon, Myanmar

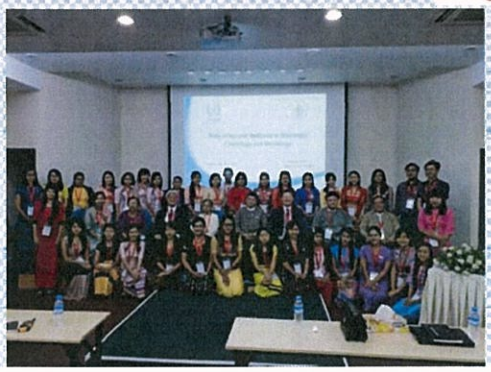
International Relationship (WARMTH)

International Relationship (WARMTH)

Mandalay

Our team

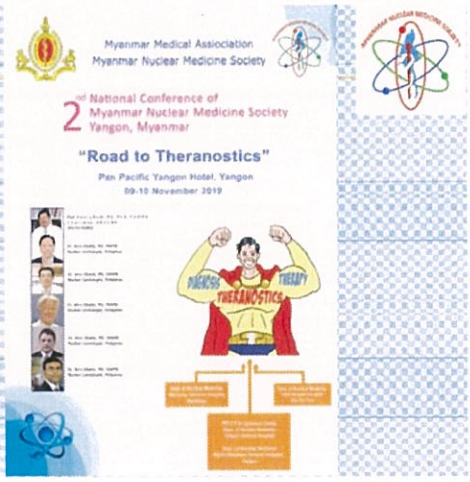
Our team



Our AIM

- To provide a wide spectrum of Nuclear Medicine services at internationally accepted standards.
- To become a center of excellence, providing efficient, up-to-date and timely Nuclear Medicine services in MYANMAR

Many Thanks for Your Attention!



Empowering Science, Impacting Lives

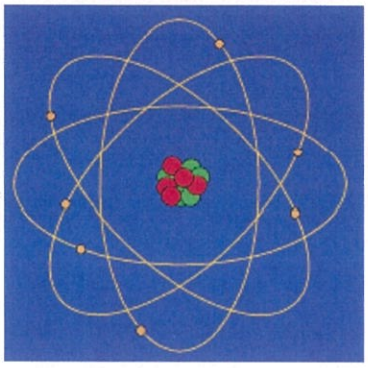
OUR BUSINESS
INTRODUCTION

2019

Presented by : Thet Zay Yar Myint

Radiance Infinity Co., Ltd
Empowering Science Impacting Lives

ATOM FOR PEACE



Empowering Science, Impacting Lives

Introduction

- We decided to enter this radiopharmaceutical market due to:
  - ✓ being only one radiopharmaceutical supplier in Myanmar until 2012
  - ✓ being limited resources (radioisotopes and cold kits) and
  - ✓ the number of patients (demand) are increasing yearly.
- The story starts with Lucky Charm Trading Pte Ltd which was incorporated in Singapore in early 2013.
- The role of Lucky Charm is for administration & International industry relationship for Myanmar market.

Empowering Science, Impacting Lives

Company Profile

Radiance Infinity Co., Ltd. was established in early 2016 and has been providing the high-quality radiopharmaceuticals for diagnosis and treatment, and services to the government hospitals and the private specialist clinics in Myanmar.

Radiance Infinity Co., Ltd. whose office is located in 8/12, Room(204), Yangon, MYANMAR has been serving with its 10 employees to supply nuclear medicine centers in Yangon, Mandalay and Nay Pyi Taw without compromising on quality and customer-oriented service.

Empowering Science, Impacting Lives

Our Value

Our core values of Leadership, Integrity, Vibrancy, Excellence and Security greatly defines how we work. These values embody the spirit and energy of Radiance Infinity, which is the foundation for our success.

It is a call to action for every employee to commit a common set of beliefs on how we conduct our day-to-day business operation with integrity and dedication for the goals that we set out to achieve.

LEADERSHIP
Pillar of strength in growth

INTEGRITY
Code of Conduct

VIBRANCY
The Spirit

EXCELLENCE
Attribute for Success

SECURITY
Basis to build trusting relationships

L I V E S

Empowering Science, Impacting Lives

Nuclear Science

The Nuclear Science business provides turnkey Hotlab setup and radiopharma_ceutical solutions for Nuclear Medicine PET/SPECT, QA tools for Radiotherapy and Diagnostic Imaging, and a whole range of Radiation Protection and Analytical Devices to the Industrial and Research markets.

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Our Business Focus

Research & Manufacturing

Homeland Security

Healthcare

Pharmaceuticals Research

Empowering Science, Impacting Lives

Our Valued

Public Hospitals:

- PET-CT & Cyclotron Center, Nuclear Medicine Department, Yangon General Hospital
- Nuclear Medicine Department, North Okkalapa General Hospital
- Nuclear Medicine Department, Mandalay General Hospital
- Nuclear Medicine Department, Nay Pyi Taw 1000 Bedded Hospital

PRIVATE HOSPITALS

- Asia Royal Hospital, Yangon
- P E R F E C T Myanmar Molecular Imaging & Therapy Center, Yangon
- Pinlon Hospital, Yangon

Empowering Science, Impacting Lives

Our Major Partners

Principals	Products
• Curium, France (IBA Cisbio + Mallinckrodt) • Monrol, Turkey • Polatom, Poland • Pharmalucence, USA • Huayi Isotopes, China • Lablogic, UK • ITG-Garching, Germany • Biodex, USA • Comecer, Italy • Hidex, Finland • TRF, Spain	• Cold kits, Iodine and Tc-99m Generators • Rubidum 82 generator for Cardiology • Gamma analyzers and radio TLC • Theranostics solution (Gallium and Lu / Y) • SPECT/PET Hotlab accessories • Hotcells and Dispensers • Synthesis Modules • Gamma counters for RIA and Scintillation Counters • Radiation protection • Iodine 131 dispensing machine • Radioactive Waste Disposal Plant

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Radioactive Regulatory and Control in Myanmar

The statement below provides the information for the current situation for Radioactive Regulatory and Control in Myanmar.

1. **DAE (Department of Atomic Energy) is the only authority to control the importation, distribution, possession and export of all radioactive materials and irradiation apparatus in Myanmar.**
2. **Myanmar FDA under Ministry of Health and Sports does not involve in the controls of radioactive substances in Myanmar currently (this includes Tc generator and Iodine-131).**
3. **DAE is using IAEA regulations as the guidelines and reference, but they do have their own implementation process in order to fit into Myanmar's needs.**

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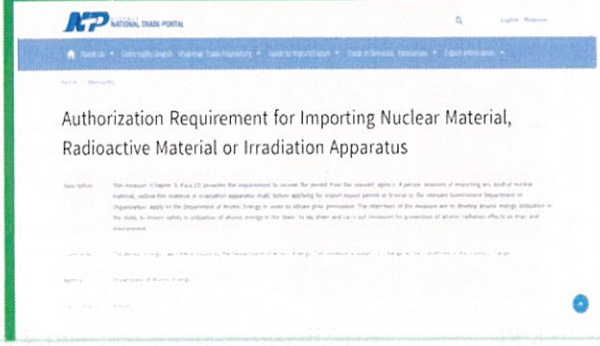
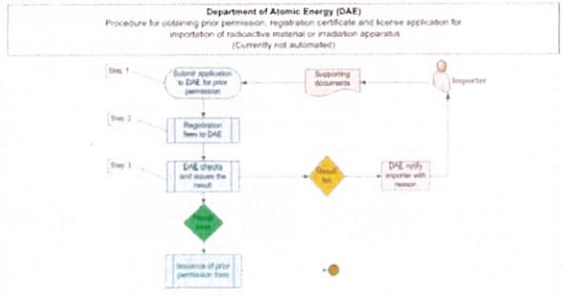
Import Requirement From Ministry of Commerce



Authorization Requirement for Importing Nuclear Material, Radioactive Material or Irradiation Apparatus

Empowering Science, Impacting Lives

Getting Import Recommendation From



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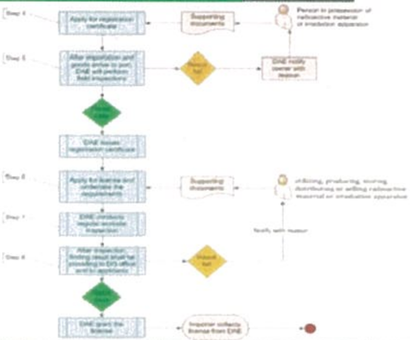
Getting End User License From DAE



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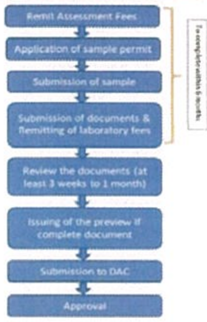
Drug Registration Procedures From FDA



*** Estimated processing time from 9 months to 1 year.

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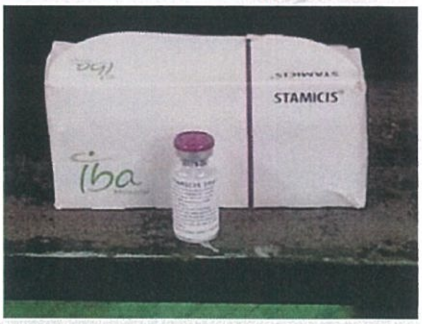
^{131}I & ^{99m}Tc Generator

Empowering Science, Impacting Lives

Radiopharmaceuticals

Empowering Science, Impacting Lives

Radiopharmaceuticals



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Our Products

COMECER

BIO-RADIOSAFETY CABINET
LAF EF4, EF5 and EF6

For Tc-99m Elution and radio-labelling work

Empowering Science, Impacting Lives

Our Products

COMECER

RADIATION SAFETY GUIDELINES

PHARMACEUTICAL GUIDELINES

RADIO - PHARMACEUTICAL SAFETY

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Our Products

BIODEX

PET Unit Dose Cabinet

L-Block Shield

Vial Shield

Shielded Waste Container

Dose Calibrator

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Our Products

Hot Lab Set-up

Turnkey Solutions

Clean room setup for Radio-pharmacy

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Our Products

CURIUM

iba

pharmalucence

POLATOM

Eczacıbaşı | monrol

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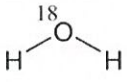
Our Products

RADIOCHEMISTRY SOLUTIONS



O-18 water

Empowering Science, Impacting Lives

Our Products

CALIBRATION SOURCES

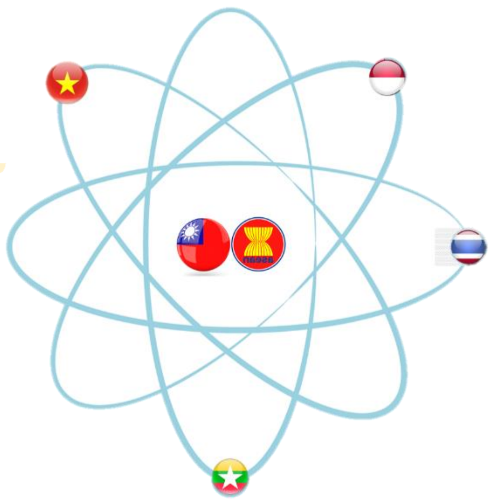
RadQual


Empowering Science, Impacting Lives
Thank You
Radiance Infinity Co., Ltd
Tel : 09261484208, 09450034409
Email : tzymyint.biz@gmail.com

附錄二 “台灣 - 東協”核醫醫藥研討會大會手冊

"台灣－東協" 核醫藥研討會
2019 Taiwan-ASEAN Nuclear Medicine Forum

Nuclear Medicine
核醫藥
เวชศาสตร์นิวเคลียร์
y học hạt nhân
pengobatan nuklir
နျူကလီးယားဆေးပညာ



大會手冊
Conference manual

主辦單位
Hosting institution

行政院原子能委員會 核能研究所
Institute of Nuclear Energy Research
Atomic Energy Council, Executive Yuan

衛生福利部
Ministry of Health and Welfare
促進全民健康與福祉

承辦單位
Organizer

國立陽明大學藥物科學院
School of Pharmaceutical Sciences
National Yang-Ming University

協辦單位
Co - Organizer

臺北榮民總醫院 核醫部
Department of Nuclear Medicine

“台灣－東協”核醫藥研討會
2019 Taiwan-ASEAN Nuclear Medicine Forum

AGENDA

2019 Taiwan-ASEAN Nuclear Medicine Forum

Date / July 26, 2019
Venue / Ho Ying Tsai Memorial Hall, Shou-Ren Building, in NYMU

Time	*Subject*	*Speaker*
09:00 ~ 09:20	Welcome remarks	Prof. Jaw-Jou Kang, Dean, School of Pharmaceutical Sciences, NYMU
	Addresses by Honorable Guests	Dr. Hei-Kuang Lee Ph.D, Deputy Director-General INER Prof. Muh-Hwa Yang, Vice President, NYMU
	Group Photo	All
		Moderator **Dr. Chih-Hsien Chang, Ph.D, Director, Sec. Isotopes Application INER**
09:20 ~ 09:50	Use of Nuclear Medicine in Taiwan	Prof. Ruoh- Fang Yen, M.D., President, Taiwan Society of Nuclear Medicine
09:50 ~ 10:20	Regulation of Nuclear Medicine in Taiwan	Ms. Mei-Chen Huang, Section Chief,Division of Medicinal Products, Taiwan FDA
10:20 ~ 10:40	**Coffee Break**	
		Moderator **Prof., Pan-Fu Kao, M.D., President, Taiwanese Society of Medical Cyclotron**
10:40 ~ 11:20	Use of Nuclear Medicine in Thailand	Prof., Yuthana Saengsuda, President, Nuclear Medicine Society Thailand
11:20 ~ 12:00	Overview of Regulatory Framework of Radiopharmaceuticals in Thailand	Ms. Achiraya Praisuwan, Professional Pharmacist, Lead GMP Inspector, Bureau of Drug Control, Thai. FDA
12:00 ~ 13:00	**Lunch**	
		Moderator **Prof. Wen-Sheng Huang, M.D., Director, Dept. Nucl Med TVGH**
13:00 ~ 13:40	Applicaion of Nuclear Medicine in the diagnosis and treatment of cancer in Vietnam	Prof., Mai Trong Khoa, Vientamese Society of Radiology and Nuclear Medicine
13:40 ~ 14:20	Regulation of Radiopharmaceutical in Vietnam	Ms. Nguyen Dieu Ha, Deputy Director of Pharmaceutical Business Management Division, DAV.
14:20 ~ 14:40	**Coffee Break**	
		Moderator **Prof., Jaw-Jou Kang, Dean, School of Pharmaceutical Sciences, NYMU**
14:40 ~ 15:20	A long Journey of Nuclear Medicine in Myanmar	Prof., Kyin Myint, President, Myanmar Nuclear Medicine Society
15:20 ~ 16:00	Experience of Nuclear Medicine Logistics in Myanmar	Mr. Thet Zay Yar Myint, CEO, Lucky Charm Co, Ltd. Singapore
16:00 ~ 17:00	General Discussion	All

OPENING

Welcome remarks

PROFESSOR, JAW-JOU KANG

Dean, School of Pharmaceutical Sciences, National Yang-Ming University
Professor, Faculty of Pharmacy, National Yang-Ming University

Honorable Guests

DR. HEI-KUANG LEE, PHD

Deputy Director-General, Institute of Nuclear Energy Research

Honorable Guests

PROFESSOR, MUH-HWA YANG

Vice President, National Yang-Ming University
Associate Professor, Institute of Clinical Medicine, National Yang-Ming University

MODERATOR

Session I

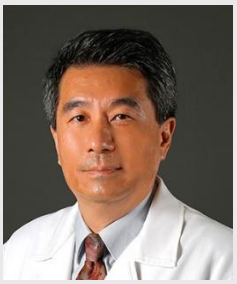
DR. CHIH-HSIEN CHANG, PHD

Director of Isotope application division, Institute of Nuclear Energy Research

Session II

PROFESSOR, PAN-FU KAO

President, The Taiwanese Society of Medical Cyclotron
Vice Chair, Faculty of Medicine, Johns Hopkins University



Session III

PROFESSOR, WEN-SHENG HUANG

Director, Department of Nuclear Medicine, Taipei Veterans General Hospital

Session IV

PROFESSOR, JAW-JOU KANG

Dean, School of Pharmaceutical Sciences, National Yang-Ming University
Professor, Faculty of Pharmacy, National Yang-Ming University

RUOH-FANG YEN

President, Society of Nuclear Medicine, Taiwan

EDUCATION

1982 MD National Taiwan University College of Medicine

2005 PhD Graduate Institute of Epidemiology, College of Public Health,

PROFESSIONAL EXPERIENCE

Director, Department of Nuclear Medicine, National Taiwan University Hospital(2015- Present)

Visiting Scholar, Department of Radiology, Harvard University School of Medicine, USA(2013/7-2013/12)

Associate Professor, Department of Radiology, National Taiwan University College of Medicine(2010- Present)

Assistant Professor, Department of Radiology, National Taiwan University College of Medicine(2006- 2010)

Lecturer, Department of Radiology, National Taiwan University College of Medicine(2002- 2006)

Attending physician, Department of Nuclear Medicine, National Taiwan University Hospital(1998- Present)

USE OF NUCLEAR MEDICINE IN TAIWAN

The utilization of nuclear medicine (NM) studies in Taiwan is greatly influenced by the reimbursement of Taiwan's National Health Insurance (TNHI), which started in 1995. Although functional and molecular characteristics of nuclear medicine imaging can provide important diagnostic information of diseases, the nuclear medicine scan is not as popular as CT and MRI. Nevertheless, depends on the clinical need and the availability of radiopharmaceutical, some of NM scan increases steadily but some decreases gradually.

From the database of TNHI, we notice that whole body bone scan, myocardial perfusion imaging and whole body PET imaging were the top three most frequent NM imaging in Taiwan. On the contrary, the utilizations of Meckel's diverticulum scan, renal scan, and lung ventilation study are significantly decreased. The number of single photon studies were 13714 per million population and PET scan were 924 per million population (6.3%) in 2012. Tc-99m radiopharmaceuticals contribute for about 67% while Tl-201 chloride contributes for about 25% of all NM studies.

As for PET tracers, Flobetaben, an F-18 amyloid tracer is the only PET tracer which has license from tFDA besides F-18 FDG at present. Other PET drugs, such as F-18 NaF, F-18 Fdopa, F-18 FLT, F-18 FCH and C-11 acetate, have been approved for clinical use according to the Regulation for Manufacturing and Compounding of PET Radiotracers, of which the first version was published on 2003. Other PET tracers use in clinical trials include amyloid (C-11 PiB, Flobetapir), tau (F-18 T807), Ga-68 DOTATOC (SSRT), Ga-68 PSMA (prostate cancer), etc.

MEI-CHEN HUANG

Section Chief, Division of Medicinal Products, Taiwan FDA

EDUCATION

M.S., Biochemistry and Molecular Biology
National Taiwan University, College of Medicine, Taiwan

PROFESSIONAL EXPERIENCE

Associate Researcher, Division of Medicinal Products, Taiwan FDA (2017-2019)

Technical Specialist, Division of Medicinal Products, Taiwan FDA (2015-2017)

Associate Technical Specialist, Division of Medicinal Products, Taiwan FDA (2010-2015)

REGULATION OF NUCLEAR MEDICINE IN TAIWAN

Radiopharmaceutical products are regulated under the same regulatory framework of other pharmaceutical products: the manufacturing, distribution and registration are regulated under the Pharmaceutical Affairs Act, and the clinical use is regulated under the Medical Affairs Act. Consultation system and expedite review pathways are also applicable for radiopharmaceutical products. However, with the special characteristics of radiopharmaceutical products, TFDA has developed specific guidelines and review requirement defined in the Regulation for Registration of Medicinal Products following international standards. Currently there are 56 radiopharmaceutical products licensed in Taiwan, one third of them are locally manufactured. On the other hand, 88% of the licensed radiopharmaceutical products are for diagnostic purpose, only 12% are for treatment use.

Positron Emission Tomography (PET) radioisotopes have a very short half-life, so the transportation is a big limitation, especially long distance. In order to meet the great amount of the demands of different PET radioisotopes, compounding of PET radioisotopes is allowed in 9 certified PET centers in different hospitals in Taiwan except for supplying by the pharmaceutical company. To ensure the quality of the compounded PET radioisotopes, the whole compounding process and the quality management need to be in compliance with the Direction and Guideline for PET Radioisotopes Compounding.

YUTHANA SAENGSUDA

President, Nuclear Medicine Society of Thailand.

EDUCATION

1975-1981 MD , Faculty of Medicine, Chulalongkorn University.
1983-1985 Thai Board of General Radiology, Faculty of Medicine, Chulalongkorn University.
1Jan-30 June 1993 6 months fellowships in nuclear medicine, St. Bartholomew Hospital , London, United Kingdom
1June-31August 1997 3months fellowships in nuclear cardiology , university of Massachusette ,Worchester, Massachusette , USA.

PROFESSIONAL EXPERIENCE

1990- 2015 Nuclear Medicine Division, Department of Radiology, Rajavithi Hospital, Rungsit university.

USE OF NUCLEAR MEDICINE IN THAILAND

Nuclear medicine in Thailand started in 1955. Professor Romsai Suwannik at Siriraj hospital was the first person to use radioisotope for medical care by using colloidal gold for palliative treatment of ascites with tumor seeding inthe peritoneal cavity of advanced ovarian cancer to relieve pain and suffer.Later, radioactive iodine was introduced for diagnosis and treatment of toxicgoiter and thyroid cancer. The following sites of NM facilities were in Chulalongkorn, Rajavithi and Chiangmai hospital respectively. Nuclear Medicine Society of Thailand was established in 1982 with 120 members and Professor Romsai Suwannik was elected as the first president. At present, this organization consists of 300 members including 90 nuclear medicine physicians and the rest are technologists, physicist, radiochemist, radiopharmacist, nurse. There are 2 regularly academic meetings an for society members in March and December each year.

Nuclear medicine in Thailand accomplished a step by step of progression and development in equipment and technology, clinical practice in term of diagnosis and treatment and research activities. Now, Thailand has 29 nuclear medicine centers : 16 in Bangkok, 3 in north, 4 in northeast, 2 in east, 2 in central part and 2 in south. 27 SPECT gamma camera, 16 SPECT/CT gamma camera and 10 bone densitometer are available in nuclear medicine centers for service. There are 11 PET CT machines with 8 machines in Bangkok, 3 in provinces, 4 cyclotrons of medium energy with 3 in Bangkok (Chulabhorn, Siriraj and BDMS hospitals) and 1 in Chiangmai. Rosatom (Russia) will supply a fifth cyclotron complex 30 MeV at Thailand institute of nuclear technology (TINT) with the government project 2018-2021 at Nakhon Nayok province.

YUTHANA SAENGSUDA

President, Nuclear Medicine Society of Thailand.

USE OF NUCLEAR MEDICINE IN THAILAND

Thai population are 69 millions with the rate of one PET/CT is for 6.27 million population. Nuclear medicine residency training started in 1989 with 5 university medical institutes for 3 years training course . Residents have to pass the exams to get Thai board of nuclear medicine set up by Thai board committee of nuclear medicine and under Royal College of Radiologist of Thailand. Consequently, 62 residents were trained up to date. At present, World Federation of Medical Education (WFME) standard of quality improvement in post graduate medical education in Thailand is settled in nearly all specialty including nuclear medicine of residency training . At the moment, all 5 nuclear medicine residency training centers have been accredited for WFME standard by national auditor team.

For nuclear medicine 59455 studies in the year 2016, the top five studies are bone scan 47.5%, total body scan (I131) 12.3%, cardiac scan 11.3%, PET oncology 9.3% and thyroid scan 7.5% which are composed of 87.9% . For 12338 radionuclide therapy among all centers, the two most procedures are I131 treatment in hyperthyroidism 70% and thyroid malignancy 29% . The rest 1% procedures are in I131 MIBG treatment, Sm-153 EDTMP, Ra-223 , Y90 microsphere, etc. Up-to-date, theranostics in nuclear medicine is in the beginning period using targeted radionuclide therapy in prostate cancer and neuroendocrine tumor among university nuclear medicine centers with promising results.

YUTHANA SAENGSUDA

President, Nuclear Medicine Society of Thailand.

USE OF NUCLEAR MEDICINE IN THAILAND

The nuclear medicine society of Thailand have signed an MOU with the nuclear medicine society of Japan since October 2016 for mutual exchange of education and research activities . It is also a great step for academic collaboration between two countries , Taiwan and Thailand , to have an MOU with each society of nuclear medicine in 2017 as well as MOU between INER and faculty of medicine , Chulalongkorn university and nuclear medicine society of Thailand .

Hopefully, nuclear medicine in Thailand will have a bright progress strongly upon the well preparedness of manpower particularly young active nuclear medicine personnel, modern equipment and new technology in both imaging and radionuclide therapy as well as academic collaborations among international institutes

ACHIRAYA PRAISUWAN

Professional Pharmacist, Lead GMP Inspector, Bureau of Drug Control, Thai FDA

EDUCATION

A doctor of pharmacy (Pharm D.) degree from the faculty of pharmaceutical science, Naresuan University, Thailand.

PROFESSIONAL EXPERIENCE

Principle investigator on a WHO-USP

Temporary Advisor to WHO on the national regulatory authority

OVERVIEW OF REGULATORY FRAMEWORK OF RADIOPHARMACEUTICALS IN THAILAND

Bureau of Drug Control, Thai Food and Drug Administration (Thai FDA) is the national regulatory authority that regulates, evaluates and monitors the safety, efficacy, and quality of therapeutic and diagnostic products available to Thailand.

The regulations related to hospital radiopharmacy, industrial radiopharmacy, centralized radiopharmacy in Thailand were controlled by Bureau of Drug Control; Thai Food and Drug Administration, Ministry of Public Health and Office of Atoms for Peace, Thailand.

The regulations on licensing, import, market authorization, and post-marketing control system in Thailand. For the Radiopharmaceuticals, supervision in Thailand may be divided into two major categories:

- Radiopharmaceutical products which are intended to be used only in medical care for a specific patient (personalized) or clinical research. These products are exempted for the marketing authorization by hospital and clinical research exemption: Drug Act B.E. 2510 Section 13 (2) “production of drugs in accordance with the prescription of a practitioners of medicine or practitioners of the healing arts for a particular patient” and “importation by ministries, sub-ministries and departments which have a duty to prevent or treat disease”.

ACHIRAYA PRAISUWAN

Professional Pharmacist, Lead GMP Inspector, Bureau of Drug Control, Thai FDA

OVERVIEW OF REGULATORY FRAMEWORK OF RADIOPHARMACEUTICALS IN THAILAND

- Radiopharmaceutical products which are intended for commercial use. According to the Drug Act B.E. 2510, Section 12 "To produce or sell a modern drug or import or order a modern drug into the Kingdom, unless he or she has obtained a license from the licensing authority. The application for and grant of a license shall be in accordance with the rules, procedures, and conditions prescribed in the Ministerial Regulation".

These products should be complied with related regulations as importation, licensing, marketing authorization, and post-marketing control (GMP compliance verification, Pharmacovigilance). Bureau of Drug Control, Thai FDA will be regulating the radiopharmaceuticals approval process under the Drugs Act, related regulations, and guidance. Before a medicinal product can be distributed and sold in Thailand, the corresponding manufacturer must have a GMP compliance status.

For GMP regulation, Thai FDA, as part of PIC/S participating authorities, conduct the GMP inspection for manufacturers following the current version of PIC/S Guideline. Moreover, the import of medicinal products should be submitting the documents to verify the GMP compliance status as per the Thai FDA Notification on GMP Clearance of Overseas Pharmaceutical Manufacturers B.E. 2560.

MAI TRONG KHOA

Vice President, Vietnamese Society of Radiology and Nuclear Medicine

EDUCATION

Oncologist and Nuclear Medicine physician at the Nuclear Medicine and Oncology center, Bach Mai Hospital, Hanoi, Vietnam.

Senior lecturer of Hanoi Medical University

PROFESSIONAL EXPERIENCE

Perform the diagnosis and treatment for patients with cancer and other diseases through nuclear medicine applications, chemotherapy, radiotherapy, targeted therapy, immunotherapy,

Teach theoretical and clinical lessons in Oncology and Nuclear Medicine for students at Hanoi Medical University

THE APPLICATION OF NUCLEAR MEDICINE IN THE DIAGNOSIS AND TREATMENT OF CANCER AND SOME OTHER DISEASES IN VIETNAM

Nowadays, in Vietnam, Nuclear Medicine has been utilized to diagnose and treat cancer and some other diseases.

The whole country has 25 SPECT, 15 SPECT / CT, 12 PET / CT, for the diagnostic. Currently, Vietnam has applied many radioactive isotopes and radioactive pharmaceuticals for treatment, such as I-131, P-32, Y-90, I-125 (radioactive seed implant), ... in the treatment of cancer, differentiated thyroid cancer, hyperthyroidism, simple thyroid goiter, bone metastatic cancer, primary and secondary liver cancer, prostate cancer.... The permanent radioactive seed implant with 125I in treatment of prostate cancer and the Selective internal radiation therapy system (SIRT) with Y-90 for the treatment of hepatocellular carcinoma and liver metastatic cancer have been successfully applied for the first time in Vietnam with high treatment efficiency and safety while improving the quality of life for patients.

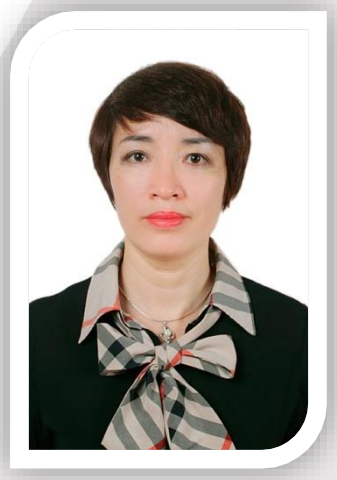
For the first time in Vietnam, PET/CT has been used to simulate radiation therapy planning for cancer patients with 3D radiotherapy, IMRT,... Targeted therapy by RadioImmunoTherapy (RIT), with Rituximab monoclonal antibodies attached to radioactive isotope 1-31I, has been used to treat lymphoma patients.

MAI TRONG KHOA

Vice President, Vietnamese Society of Radiology and Nuclear Medicine

THE APPLICATION OF NUCLEAR MEDICINE IN THE DIAGNOSIS AND TREATMENT OF CANCER AND SOME OTHER DISEASES IN VIETNAM

All nuclear medicine facilities in the country have applied the majority of radioactive isotopes and routinely marked compounds in the world for the diagnosis and treatment of diseases. This source of Radiopharmaceutical is partly produced at Da Lat Nuclear Reactor, the rest must be imported from abroad. The whole country currently has 12 PET/CT units and 5 cyclotrons including 3 active cyclotrons and 2 cyclotrons without an active license. There are a lot of new radiopharmaceuticals, marked compounds for diagnosis and treatment.



NGUYEN DIEU HA

Deputy Director of Pharmaceutical Business Management Division,DAV

EDUCATION

Master of Pharmacist

PROFESSIONAL EXPERIENCE

Control of Radiopharmaceutical, Narcotics drug, Psychotropic substance and Precursor

REGULATION OF RADIOPHARMACEUTICAL IN VIETNAM

Radiopharmaceutical (Radioactive Drug): Drug that contains radionuclides used for diagnosis, treatment of diseases in humans or medical-biological research, including:

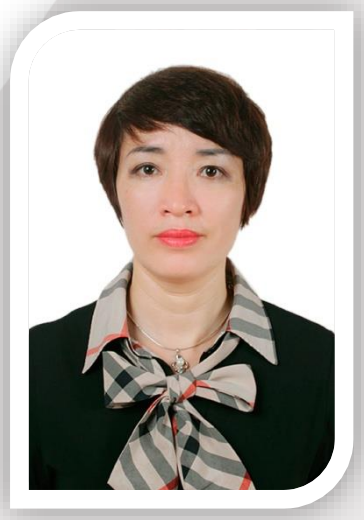
Radioactive isotopes or Radioactive isotopes combined with tracers.

I. CONDITIONS FOR TRADING IN RADIOPHARMACEUTICAL (Article 34 Law on Pharmacy)

1. *Any establishment trading in radiopharmaceuticals must be approved in writing by a pharmacy authority (Certificate of Satisfaction of Conditions for trading in pharmaceuticals) .*
2. *Establishment trading in radiopharmaceuticals must fulfil:*
   - A. Every condition specified in Article 33 of Pharmacy Law corresponding to the conditions for each type of establishment:
     - Material/ technical facilities and personnel resources;
     - Pharmacy practice certificates of the person in charge of pharmacy expertise and the persons holding the specified positions
   - B. Security Measures (Articles 43- 48): Material/ technical facilities ; Personnel resources; Mechanisms for Drug Delivery, Transportation, Buying and Selling, Report, Disposal 3. Satisfy the conditions specified in the Law on Atomic Energy and relevant legislative documents.

II. Radiopharmaceuticals may only be used for people when *Marketing approval (Drug Registration No.) is granted*

1. *Drug Import license is granted (if no Drug Registration No. granted yet)*
2. *Public health establishments: buying radio-pharmaceuticals in the form of Drug Bidding*



NGUYEN DIEU HA

Deputy Director of Pharmaceutical Business Management Division,DAV

REGULATION OF RADIOPHARMACEUTICAL IN VIETNAM

III. Proposals and Recommendations

The management of radiopharmaceuticals should be strengthened to ensure drug quality, safe and rational use for patients instead of just managing radiation safety as before.

1. It is necessary to coordinate and unify between the state management over healthcare and the state management over radiation safety, in order to facilitate businesses and drug using establishments to avoid overlapping regulations that waste time and resources of enterprises
2. Proposal: amending and supplementing Laws and relevant legal documents to unify the management between the Ministry of Health and the Ministry of Science & Technology.
3. Strengthening quality control for both locally produced radiopharmaceuticals and imported radiopharmaceuticals.
4. Enhancing information exchange and training between state management agencies on health and state management agencies on radiation safety.
5. Need support from International Atomic Energy Agency (IAEA) and regulators of radiopharmaceuticals of countries in the world, particularly countries in our region.

KYIN MYINT

President, Myanmar Nuclear Medicine Society

EDUCATION

MBBS, M. Sc. (Nuclear Medicine), FANMB

PROFESSIONAL EXPERIENCE

Served the country as a Nuclear Medicine Physician under the Ministry of Health, MYANMAR, Participating in a number of IAEA organized Fellowships, Regional Training courses, Meetings, Scientific Visit in Nuclear Medicine field. (1989-2016)

National project Coordinator of IAEA TC project MYA6029 (2014-2016)

President, Myanmar Nuclear Medicine Society, Myanmar Medical Association (2016-2020)
Regional Principal of AOSNM (2017 – 2019)

Board of Director, AOFNMB

Member of WARMTH, WFNMB, AOFNMB, SNMMI

A LONG JOURNEY OF NUCLEAR MEDICINE IN MYANMAR (THE PAST & PRESENT)

Background: The Department of Radioisotope, the forerunner of future Department of Nuclear Medicine was founded at Yangon General Hospital in 1963, following the visit of Dr. E. H. Belcher, the then Head of the Division of Life Sciences of the International Atomic Energy Agency (IAEA), and consultation with local health authorities (Ministry of Health, Myanmar). Continuous development of Rectilinear scanner (1966), Three-probe scintillation detector (1968), Planar Gamma Camera and RIA automatic well-counter (1974), SPECT gamma camera (2000), SPECT-CT (2014), PET-CT and 18 MeV CYCLOTRON (2015) provide effective clinical uses of Radio-isotopes for the people of Myanmar, improving health-care status. Radioiodine (131I) therapy for thyrotoxicosis and Differentiated Thyroid Carcinoma has been done since 1974. Postgraduate program of one-year Diploma course has started in 1997 and upgraded to three-year Master degree in 2007 in affiliation with University of Medicine 1, Yangon. Myanmar Nuclear Medicine Society (MNMS) was formed in 2014 and the present membership status is about 50. Departments of Nuclear Medicine in Myanmar are planning to introduce PRRT and Theranostics with existing hybrid imaging facilities (SPECT-CT & PET-CT).

Methodology: The Government of MYANMAR in collaboration with International Atomic Energy Agency (IAEA) has played a pivotal role not only for successful implementation of the projects, but also for sustainable growth and upgrading of Nuclear Medicine services in MYANMAR.

Conclusion: Myanmar Nuclear Medicine society is a major steering body to communicate with other allied societies for the upgrading and sustainable growth of Nuclear Medicine services in Myanmar.

THET ZAY YAR MYINT

CEO, Lucky Charm Co, Ltd.
Singapore

EDUCATION

B.E. (Electronics)

M. Sc. (Mechatronics)

PROFESSIONAL EXPERIENCE

Hardware & Software engineering

Radiopharmacueticals & Importing Radio-Isotopes to MYANMAR through Radiance Infinity Co. in Yangon, Myanmar

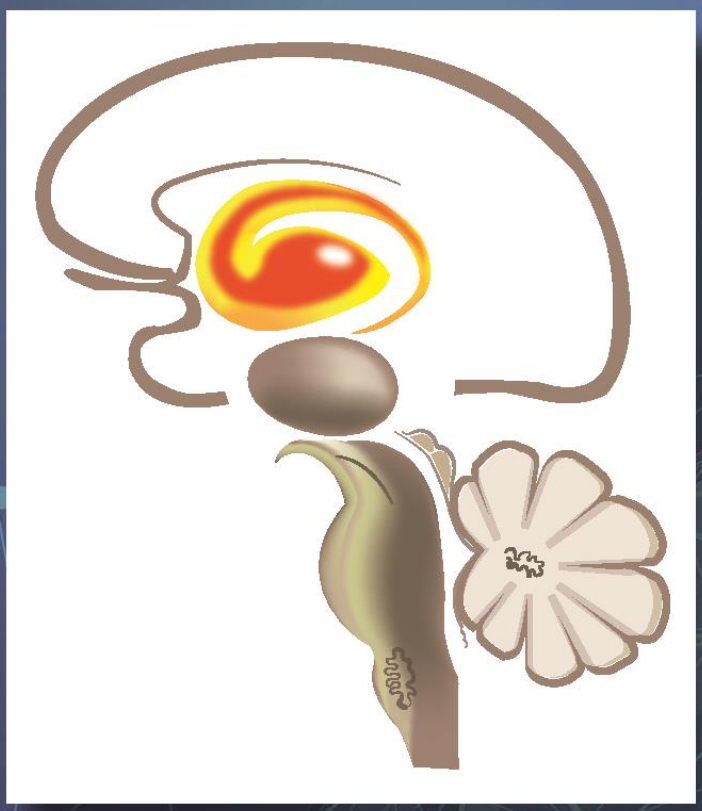
EXPERIENCE OF NUCLEAR MEDICINE LOGISTICS IN MYANMAR

Background: Republic of the Union of Myanmar, mainland of about 50 million populations, , and radiopharmaceuticals need to be imported from abroad via the Myanmar citi has 4 public and 3 private Nuclear Medicine departments. All the Nuclear Medicine Instrumentations, Radioisotopes zen's company. There are three local companies running for the Nuclear medicine infrastructure of Gamma Camera, SPECT-CT, PET-CT and Cyclotron (such as, SIEMENS, GE, Philips, and IBA). But, there was only one local company running supply of radio-isotopes and radiopharmaceuticals for many years. All the consumables were imported from ANSTO, Australia with many limitations.

Methodology: Knowing the limitations and problems encountered in the country, we find out other possible alternatives. We achieved the import licenses from Department of Atomic Energy (DAE) and Ministry of Trade with the support of local consumers and confidence from the radiopharmaceuticals companies in abroad (Mostly from the west). Food & Drug Authority (FDA) under the Ministry of Health & Sports is finding out the way to handle radiopharmaceuticals, but not approved yet.

Results: We become the sole distributor of radio-isotopes and radiopharmaceuticals in Myanmar, because of cost-effectiveness. We have already run the business for three years.
Conclusion: Nuclear Medicine services are booming up among the clinicians in the management of cancer and other non-communicable diseases (NCD). FDA of Myanmar is finding out the best way for regulation of radiopharmaceuticals, regarding effective use of radio-isotopes and radiopharmaceuticals in the health-care system of Myanmar.

TRODAT-1 Kit



Quality imaging of dopamine transporters,
More accessible and more economical

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