## Sheet1
| Unnamed: 0 | SPECT Biomarker Committee | Unnamed: 2 | Unnamed: 3 | Unnamed: 4 | Unnamed: 5 | Unnamed: 6 | Unnamed: 7 |
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| NaN | Quantifying Dopamine Transporters with 123Iodine Labeled Ioflupane in Neurodegenerative Disease | NaN | NaN | NaN | NaN | NaN | NaN |
| NaN | Point-by-point response to public comments about Version 1.0 of our Profile of 4Q2016 | NaN | NaN | NaN | NaN | NaN | NaN |
| NaN | draft of 06 June 2017 | NaN | NaN | NaN | NaN | NaN | NaN |
| NaN | NaN | NaN | NaN | NaN | NaN | NaN | NaN |
| # | experts' names | Line # | Section # | issues raised by public experts | suggestions raised by public & their editorial comments | BC response | (concrete) proposal |
| 1 | Iida (Japan) | 455 | NaN | CT-based mu maps. There should be criteria and procedures on how to evaluate the adequacy of CT-derived attenuation coefficient maps. | A standard phantom may be of help. The extent to which the attenuation coefficient value is consistent among systems would be of interest and should help improve future studies. Beam hardening procedures, the intrinsic energy spectra of X-rays, and calibration procedures could differ among vendors, and if this is the case, these may be sources of errors. | We agree that consistency of attenuation coefficients across systems is important; however, this would require a attenuation calibration phantom with multiple different tissue objects which most would not possess. Furthermore, smoothig applied to the attenuation maps by vendors to match SPECT resolution makes interpretation diffcult. Instead we will focus on assessing unifromity in the striatal phantom as a means of testing the adequacy of the attenuation correction. | Text was added to profile in Sections 4.2.5 and in Table 3.8.2. |
| 2 | Iida (Japan) | 420 | see also Line 695 | Sensitivity and minimal counts are important issues. This is particularly the case when using a low-sensitivity system, and when multiple time frame acquisition is carried out. Pixel counts are stored as integers in DICOM format, even after uniformity and center-of-rotation corrections. Systematic bias can occur when counts are small. Assessment of absolute sensitivity is informative to understand the sensitivity of SPECT came-collimator combinations. A conversion factor from SPECT counts to Bq/mL is feasible (Becquerel calibration factor or BCF) and its inverse corresponds to the sensitivity of the system. Minimal scan duration for the SPECT scan can then be defined for each given system–collimator combination [9]. | Assess absolute sensitivity. Specify a minimal scan duration for each system-collibmator combination. | We agree that this is an important issue. Although, instead of specifying a minimal scan duration, which will vary with system and collimator, we have specified a minimal count requirement of > 1.5 million. This number was based on manufacturer recommendations and a previously published SNM guidelines document. (The EANM guidelines recommend > 3 million counts). As part of a QIBA sponsored groundworks project we further evaluated the minimal count requirements for accurate and precise estimation of the SBR. Initial results from this striatal phantom study, performed at 0.5,1,2, and 3 million total counts, are showing that the bias and variance of the measured SBR are similar for count levels down to 1 million and only the 0.5 million level results in a statistically significant difference in bias and variance. Hence, we are inclined to stay with our recommendation of > 1.5 million total counts. This would require 25 – 45 min acquisition on a typical dual head camera with LE collimators. Given that the uptake will vary on a patient to patient basis a calibration factor will not be particularly helpful here. | Text added in profile Section 3.6. |
| 3 | Iida (Japan) | 215 | NaN | We agree the absolute quantitation in Bq/mL is beyond the scope of this QIBA profile for DaT-SPECT. This is attributed to variation of the arterial input function among clinical subjects. Reconstruction software for deriving such information is not consistently provided by vendors, thus this evaluation is demanding and may therefore be omitted. However, this evaluation provides essential information for determining the quality of attenuation and scatter correction procedures. If a syringe containing I-123 solution is scanned, the data contains only small attenuation and scatter components, while a cylindrical phantom with diluted I-123 solution from that syringe contains as much attenuation and scatter as in clinical scans. Applying the scaling factor of reconstructed images to Bq/mL, as defined based on the reconstructed images of the syringe, averaged pixel counts in units of Bq/mL provide adequate corrections by referring pixel counts to the ideal radioactivity concentration. This can also be done with the Striatum phantom by referring the uniform area. | We would like to suggest that the camera-specific quality of corrections be evaluated for each system. The data should also be useful if one wishes to investigate the adequacy of a reconstruction software program that is designed to reduce camera-specific variation. It should be noted, however, that errors in the head contour in clinical scans are a different issue that should be separately evaluated. | We agree that consistency of corrections across systems should be assessed within the profile. Tomographic uniformity is addressed in Section 4.2.4. To assess corrections in a more clinical setting we have now added a section to assess adequacy of corrections by evaluating uniformity in the striatal phantom (Section 4.2.5). | Text was added to profile in Sections 4.2.5 and in Table 3.8.2. |
| 4 | Iida (Japan) | NaN | 4.2.3 | The BIG VOI approach has been shown to provide SBR values for the whole striatum with minimal contribution of the partial volume effect, and small systematic errors are attributed to different spatial resolutions. However, errors were still observed that were dependent on the specific SPECT systems used, even though the same reconstruction software was utilized [3]. This has been explained by errors in edge detection, and also noise enhancement in TEW scatter correction. Attenuation correction, including the head contour identification, and assessment of scatter correction are important in order to understand camera-specific errors. | Core lab analysis using a single reconstruction package would be of value. | Although the use of a single reconstruction package would be of value to CRO's working on multi-center trials, the targetted audience of this profile extends beyond this to also include individual users of DAT SPECT imaging. In this instance a unified reconstruction package is outside the scope of the QIBA mandate. However, a paragraph has been added in section 3.7.1 highlighting that it can be beneficial to use a core lab and/or common reconstruction in certain scenarios because it provides lower variability. | We have added text and a reference in section 3.7.1 highlighting that it can be beneficial to use a core lab and/or common reconstruction in certain scenarios. |
| 5 | Iida (Japan) | NaN | 4.2.4 | suitability for basal ganglia imaging — re: phantom evaluation. A striatum phantom should have a reasonable structure and size that can generate as much penetrating photons and scatter as clinical scans, otherwise the accuracy of correction is overestimated (error can be underestimated). | Particular factors that should be taken into account are the following: (a) adequacy of the head contour identification if the attenuation map is generated from emission data, (b) adequacy of absolute mu values prepared using a CT-based technique, and (c) adequacy of correction for scatter and penetrating photons. It should be noted that inaccurate correction for scatter could be compensated for by changing the effective attenuation coefficient values, in order to provide homogeneous distribution for uniformly distributing phantom. In such cases, the contrast between the striatum and background counts are altered. Systematic analysis needs to be performed. | Thank you. We agree that Chang AC contours and mu values together with the accuracy of CT AC are potential sources of error in quantification. In section 4.2.3 we already perform tomographic uniformity measurements to assess the quality of the corrections, and beyond that have chosen to focus on the outcome of our measurand (SBR) with the striatal phantom rather than focusing directly on the accuracy of the corrections. However, we agree that there is an opportunity to expand this element of the profile to look at uniformity in part of the striatal phantom rather than the cylinder given that the cylinder does not have bone equivalent structures and has given that it has variable contour definitions. | Text was added to profile in Sections 4.2.5 and in Table 3.8.2. |
| 6 | Iida (Japan) | 800 | NaN | Missing references. | 1.Tossici-Bolt L, Dickson JC, Sera T, de Nijs R, Bagnara MC, Jonsson C, et al. Calibration of gamma camera systems for a multicentre European 123I-FP-CIT SPECT normal database. Eur J Nucl Med Mol Imaging 2011;38(8):1529-40. | Thank you for contributing these important manuscripts to our References section. Just as the reviewers suggested, we have now added every one of them. | References added. |
| 6 | Iida (Japan) | 801 | NaN | NaN | 2.Tossici-Bolt L, Hoffmann SM, Kemp PM, Mehta RL, Fleming JS. Quantification of [123I]FP-CIT SPECT brain images: an accurate technique for measurement of the specific binding ratio. Eur J Nucl Med Mol Imaging 2006;33(12):1491-9. | Thank you for contributing these important manuscripts to our References section. Just as the reviewers suggested, we have now added every one of them. | References added. |
| 6 | Iida (Japan) | 802 | References | Missing references. | 3.Buchert R, Kluge A, Tossici-Bolt L, Dickson J, Bronzel M, Lange C, et al. Reduction in camera-specific variability in [(123)I]FP-CIT SPECT outcome measures by image reconstruction optimized for multisite settings: impact on age-dependence of the specific binding ratio in the ENC-DAT database of healthy controls. Eur J Nucl Med Mol Imaging 2016;43(7):1323-36.\n4.Koch W, Unterrainer M, Xiong G, Bartenstein P, Diemling M, Varrone A, et al. Extrastriatal binding of [(1)(2)(3)I]FP-CIT in the thalamus and pons: gender and age dependencies assessed in a European multicentre database of healthy controls. Eur J Nucl Med Mol Imaging 2014;41(10):1938-46.\n5.Nobili F, Naseri M, De Carli F, Asenbaum S, Booij J, Darcourt J, et al. Automatic semi-quantification of [123I]FP-CIT SPECT scans in healthy volunteers using BasGan version 2: results from the ENC-DAT database. Eur J Nucl Med Mol Imaging 2013;40(4):565-73. | Thank you for contributing these important manuscripts to our References section. Just as the reviewers suggested, we have now added every one of them. | References added. |
| 6 | Iida (Japan) | 803 | NaN | Missing references. | 6.Thomsen G, Knudsen GM, Jensen PS, Ziebell M, Holst KK, Asenbaum S, et al. No difference in striatal dopamine transporter availability between active smokers, ex-smokers and non-smokers using [123I]FP-CIT (DaTSCAN) and SPECT. EJNMMI Res 2013;3(1):39. | Thank you for contributing these important manuscripts to our References section. Just as the reviewers suggested, we have now added every one of them. | References added. |
| 6 | Iida (Japan) | 804 | NaN | Missing references. | 7.Varrone A, Dickson JC, Tossici-Bolt L, Sera T, Asenbaum S, Booij J, et al. European multicentre database of healthy controls for [123I]FP-CIT SPECT (ENC-DAT): age-related effects, gender differences and evaluation of different methods of analysis. Eur J Nucl Med Mol Imaging 2013;40(2):213-27. | Thank you for contributing these important manuscripts to our References section. Just as the reviewers suggested, we have now added every one of them. | References added. |
| 6 | Iida (Japan) | 805 | NaN | Missing references. | 8.Iida H, Narita Y, Kado H, Kashikura A, Sugawara S, Shoji Y, et al. Effects of scatter and attenuation correction on quantitative assessment of regional cerebral blood flow with SPECT. J Nucl Med 1998;39(1):181-9. | Thank you for contributing these important manuscripts to our References section. Just as the reviewers suggested, we have now added every one of them. | References added. |
| 6 | Iida (Japan) | 806 | NaN | Missing references. | 9.Iida H, Nakagawara J, Hayashida K, Fukushima K, Watabe H, Koshino K, et al. Multicenter evaluation of a standardized protocol for rest and acetazolamide cerebral blood flow assessment using a quantitative SPECT reconstruction program and split-dose 123I-iodoamphetamine. J Nucl Med 2010;51(10):1624-31. | Thank you for contributing these important manuscripts to our References section. Just as the reviewers suggested, we have now added every one of them. | References added. |
| 7 | Mori | 456 | NaN | Scatter correction | Should allow for the scatter correction methods which iteratively estimate scatter components using | Thank you for this comment. We agree that (ECF) methods such as model-based or Monte Carlo scatter compensation that updates the scatter estimate during the reconstruction process is better. These are not avaialble on most clinical platforms. WSince the goal is to maximise the accessibility of the profile, we have restricted ourselves to requiring TEW. We will however include references to alternative scatter compensations and indicate that the use of these is optional and may be desirable for improved accuracy and precision. | We have expanded on current statement on other scatter correction options and have included model based and Monte Carlo based references (Section 3.7.1). |
| 8 | Mori Okazawa (Japan) | 473 | NaN | Standardization of quantitative biomarker for Dat-SPECT is challenging. One reason is attributed to a large scale of variation of background counts. | The best approach should be to verify a common reconstruction program applicable at each clinical site which should be able to read and reconstruct the scanner-raw data (projection data). | Thank you for your comment. This has also been discussed in response to the issue in 4.2.3 highlighted by Iida above. The use of a common reconstruction program is highly advantageous in multi-center trials. However, QIBA encourages diversity as a way of promoting innovation. Clinical trial sponsors, core labs, and clinical networds are welcome to take a different position, but this profile is intended to serve a diverse constituency who may be using many different software programs that conform to our profile. | We have added text and a reference in section 3.7.1 highlighting that it can be beneficial to use a core lab and/or common reconstruction in certain scenarios. |
| 9 | Matssuo (Japan) | NaN | NaN | SBR for big VOIs as proposed by Tossici-Bolt (EJNMMI, 33:1491-1499,2006) is widely utilized in Japan as a quantitative index. | There should be also a focus of evaluating reproducibility etc on this method. | We agree that the large VOI method of Tossici-Bolt may be optimal for certain clinical investigations. However, the generous dimensions of the VOI outline of this method, aimed at including all counts within the entire striatum, precludes separate estimation of SBR for sub-structures such as caudate and putamen. We believe the ability to separately analyze sub-regions of the striatum, as outlined in the profile, is important since in most neurodegenerative disorders the loss of DaT activity is first observed in the posterior aspect of the putamen | No change to the current profile entitled, "Ioflupane". |
| 10 | Matssuo (Japan) | 130 | NaN | DaTSCAN should be useful not only for Parkinson’s disease, but also for Dementia with Lewy Bodies disease. | This is still an investigation phase, but I do hope that this could be mentioned in the profile. | Thank you. Your point is well taken. The committee was thinking much like you when the name of the Profile was changed from "Parkinson's disease" to "Neurodegenerative Disorders". We agree that we did not go far enough, as your point was also made by several of our colleagues. | The text has now been expanded in several sections as suggested to clarify that this Profile can be applied to the study of other neurodegenerative disorders that affect dopamine transporters, including Diffuse Lewy Body Dementia (DLBD). |
| 11 | Matssuo (Japan) | NaN | NaN | SPECT acquisition parameters are different. How to standardize is a little tricky, as results can be affected by detailed parameters. | It should be noted that the software itself could be different even when the same parameter values are set. Ideally those differences should be assessed very carefully | We agree that consistency of acquisition and processing parameters is important. A major goal of this profile is to specify a set of parameters that can achieve the specified repeatability and accuracy claims. Thus, the profile sets minimum values on some parameters. At the same time, the profile should not restrict users from achieving better accuracy and precision in the name of achieving better repeatability across centers. We have tried to achieve this balance in the profile recommendations. | No change to the current profile entitled, "Ioflupane". |
| 12 | Matssuo (Japan) | 420 | NaN | Among many technical issues which are important to achieve reasonable reproducibility, the fact is that results are highly affected by the selection of collimator attributed to the penetrating high-energy photons. Physical suppression is essential and the best approach, in order to minimize effects of the penetrating photons. | As an extension of developing a guideline for I-123 labeled cardiac SPECT imaging, use of I-123 dedicated collimator should be encouraged. In the cardiac project, use of middle-energy type collimator provided better results (Ann Nucl Cardiol 20151(1):27-24). | We agree that dedicated I-123 brain collimators would be ideal. However, there is too much diversity among our constituents to mandate any particular collimator at this time; we have only specified the minimum quality attributes that all conforming collimators must possess. We also agree that extending to cardiac imaging would be desirable. However, we believe that is beyond the scope of the present project. Planar imaging is typically used in quantitative I-123 MIBG innervation imaging, and this has different requirements in terms of the collimator than striatal imaging, the focus of this profile. We believe, and the evidence supports, that striatal imaging requires the use of high resolution collimators, and that the additional septal penetration has a smaller impact than on planar imaging. However, it is true that some low-energy collimators have more penetration than others. We have included limitations on penetration in the profile. (Make sure that this is in the profile). Groundworks projects on ME collimators are ongoing | No change to the current profile entitled, "Ioflupane". |
| 13 | Matssuo (Japan) | 420 | NaN | Different image analysis software can be a source of variability that could potentially confound multi-center trials and limit the reproducibility between sites. | The use of common software should be effective. Of the note is that QSPECT software demonstrated the best results in reproducibility of SBR values. This was due to the better performance in the head contour determination and also minimal enhancement of statistical nose in the scatter subtraction process. Hope this software can contribute to this project. | While we appreciate the importance of using good methods, it is beyond the mandate of the QIBA process to specify specific software packages. This would have the adverse effect of reducing innovation and eliminating the potential for future improvements in methodlogy. | We have added text and a reference in section 3.7.1 highlighting that it can be beneficial to use a core lab and/or common reconstruction in certain scenarios. |
| 14 | Matssuo (Japan) | 455 | NaN | Using Chang's uniform ellipse for attenuation correction could introduce problems. Human heads are variable in size, shape, and skull thickness. Traumatic and surgical wounds can make the assumption of uniform attenuation precarious. | CT should give better head contour when using vendor software. There are many clinical institutions which have hybrid CT/SPECT cameras. Therefore CT-based attenuation correction should be utilized for the quantitative analysis. The impact of using CT-mu can be relatively easily evaluated. | We agree that CT-based attenuation compensation is desirable. However, in order to make the profile applicable to as wide a user base as possible, we have not limited the profile to hybrid systems. Studies performed as part of the process of defining this profile indicated that attenuation compensation based on the assumption of uniform attenuation (e.g., using the Chang method) provides reasonably good accuracy of the SBR. The profile does recommend CT-based correction where-available to provide more accurate attenuation maps and the potential to reduce user variability. | No change to the current profile entitled, "Ioflupane". |
| 15 | Matssuo (Japan) | 535 | NaN | Some approaches to image analysis might be best fit-for-purpose under some circumstances, but less than ideal in other contexts | The image analysis using DAT view software (Nihon Medi-Physics, Tokyo), which is based on a method developed by Tossici-Bolt et al., is a measurement technique without anatomic standardization using bilateral whole striatal VOIs and the whole brain except for the striatal regions as a reference (Tossici-Bolt method: T-B method). | We agree that the large VOI method of Tossici-Bolt may be optimal for certain clinical investigations. However, the generous dimensions of the VOI outline of this method, aimed at including all counts within the entire striatum, precludes separate estimation of SBR for sub-structures such as caudate and putamen. We believe the ability to separately analyze sub-regions of the striatum, as outlined in the profile, is important since in most neurodegenerative disorders the loss of DaT activity is first observed in the posterior aspect of the putamen | Informative text will be added to alert the QIBA constiuency that the design specifications of the image analysis software described in this profile are highly context specific. Other software might be better fit-for-purpose in some contexts, but it will be incumbant on the users to justify their choices. Otherwise, no change to the current profile entitled, "Ioflupane". |
| 16 | Japan | NaN | Inclusion Criteria | The context in which the discriminatory claim holds should be narrowed. There are more problems that can mimic Parkinson's disease than listed in the current version of the Profile. The description of a comparison group of healthy human participants should be expanded. | Suggest expansion of the selection criteria for the healthy comparison group as follows: 1）Healthy Japanese volunteers, 30 to 90 years old\n 2）Unified Parkinson’s Disease Rating Scale（UPDRS） PartⅢ\n total score 0 (younger than 60 years old) or less than 5 (older subjects)\n 3) Beck Depression Inventory (BDI)\n BDI-I less than 10\n BDI-II less than 12\n 4) Japanese Version of The Montreal Cognitive Assessment (MoCA-J)\n above 26 | Thank you for the suggestion. We agree that the selection of the comparison group is critical. Most of us require screening laboratory studies, urine toxicology assessments, and MRI scans before evaluating patients in our clinical practices or enrolling them in clinical trials. We agree that matching the demographics of the control group with the patient group is important. However, we find it challenging to specify "one size fits all" in this particular profile. For example, we expect this Profile to be useful in studies of novel neuroprotective drugs for familial Parkinson's related to LARK mutations, some of which have early ages of onset. | The text has now been expanded in several sections as suggested to clarify that selection of the control group is mission critical and in some cases, highly dependent on context. |
| 18 | Japan | NaN | Claim 1c: Cross sectional. Discrimination | Article for Discrimination | Computed-tomography-guided anatomic standardization for quantitative assessment of dopamine transporter SPECT. Yokoyama K, et al. Eur J Nucl Med Mol Imaging (in press). In our above recent article, 80% or less than the SBR value in the whole striatum50% or less than the value in the posterior putamen for age-matched control are also diagnostic. However diagnostic power of posterior putaminal SBR may be lower than that of the whole striatal SBR, since even normal aging shows greater SBR decline in posterior putamen than in anterior putamen or caudate. | Points well taken. | Text has been added to line 173. Reference has been added to reference section. |
| 19 | Japan | 80 | NaN | Q. Measured: specific binding ratio or percent injected dose per gam? | 1)SBR value should be calculate and compared at the condition of same SPECT spatial resolution. Or, 2)Total accumulation of DaT to striate body should be measured as absolute activity in the unit of MBq. | We agree that consistency of acquisition and processing parameters is important. A major goal of this profile is to specify a set of parameters that can achieve the specified repeatability and accuracy claims. Thus, the profile sets minimum values on some parameters. At the same time, the profile should not restrict users from achieving better accuracy and precision in the name of achieving better repeatability across centers. We have tried to achieve this balance in the profile recommendations. | No change to the current profile entitled, "Ioflupane". |
| 20 | Japan | 100 | NaN | In most clinical imaging contexts where the question is about a neurodegenerative disorder, the loss is first observed in the most posterior aspect of the putamen, and then seems to march anteriorly, with left and right sides showing asymmetric changes. Since the caudate and putamen size are smaller than SPECT spatial resolution, SPECT values of the caudate and putamen are affected by partial volume effects. | The text of the Profile should be expanded to note that the max and average SBR values of caudate or putamen in SPECT images are incorrect. These are depending on collimator, SPECT system, reconstruction method, attenuation correction, etc. | We agree that collimator, SPECT system, reconstruction, corrections etc. affect the value of our measurand. However, claim 1a requires SBR be corrected for known bias which can be derived from striatal phantom work. Claim 1b is based on the ratio of caudate to putamen which should be less affected by these factors given that they are similar in volume. | The informative text has been expanded as suggested. However, there is no change to the declarative text for this version of the profile. |
| 21 | Japan | 155 | NaN | This claim does not mandatorily require the bias to be corrected for. | A major contributor to the bias is partial volume effects, the only solutions for this issue are 3)SBR value should be calculate and compared at the condition of same SPECT spatial resolution; or, 4)Total accumulation of DaT to striate body should be measured as absolute activity in the unit of MBq. | We disagree. Within parenthesis in Claim 1a, and also in the paragraph below the claim, the profile does require that bias be corrected for. Claim 1b does not require the bias to be corrected for, given that the partial volume effect will affect the caudate and putamen similarly. | No change to the current profile entitled, "Ioflupane". |
| 22 | Japan | 215 | NaN | However, absolute quantification is beyond the scope of this profile. | Why absolute quantification is beyond the scope of this profile? This is so important and necessary. Since the caudate and putamen size are smaller or equal than SPECT spatial resolution, SPECT values of the caudate and putamen are affected by partial volume effects, SBR is measured with big error. | We agree that measured SBR is associated with a large bias caused by partial volume effects. However, in our profile, for Claim 1a we recommend that SBR is corrected for bias, while in Claim 1b, partial volume effect bias in caudate and putamen will be similar, so correction is not absolutely necessary. | No change to the current profile entitled, "Ioflupane". |
| 23 | Japan | 420 | NaN | If triple energy-window based scatter correction is to be used, two additional narrow windows (typically 7%) adjacent to the photopeak or as recommended by the system manufacturer shall be used. | TEW equivalent efficacy scatter correction is necessary. | We agree that scatter compensation is important. We recommended scatter compensation in the profile. We agree that TEW is useful, but leave room for future innovation and implementation of more sophisticated and potentially more accurate methods in the future. While we recommend scatter correction, such a correction has less of an impact for Claim 1b, and Claim 2. | A section was added to Table 3.7.2 |
| 24 | Japan | 450 | NaN | The attenuation correction can be implemented either using iterative (e.g., OSEM), analytical (e.g., Tretiak-Metz), or approximate (e.g., Chang 0) algorithms. Approximate and analytic attenuation correction methods typically use an estimated map and assume uniform attenuation. | As this condition reduces the accuracy of measurement, it should be addressed as premises for inaccurate measurement methods. | We agree that CT-based attenuation compensation is desirable. However, in order to make the profile applicable to as wide a user base as possible, we have not limited the profile to hybrid systems. Studies performed as part of the process of defining this profile indicated that attenuation compensation based on the assumption of uniform attenuation (e.g., using the Chang method) provides reasonably good accuracy of the SBR. The profile does recommend CT-based correction where-available to provide more accurate attenuation maps and the potential to reduce user variability. | No change to the current profile entitled, "Ioflupane". |
| 25 | Japan | 455 | NaN | The use of measured attenuation maps and iterative reconstruction is preferred. Measured attenuation maps obtained from CT images should have the attenuation values translated so that they are appropriate for 159 keV and be registered to the emission images with an accuracy of better than 2 mm. | CT based attenuation correction(CT-AC) is the best-method of the attenuation correction. Based on CT-AC, SPECT value can be in the unit of MBq/ml or μCi/ml.\n Comments from Prof Shinro Matsuo, MD, PhD | We agree that CT-based attenuation correction is preferred. However, the representation of images in terms of activity concentration is not within the scope of this profile, and discordant with the typical SBRs used in the literature. | No change to the current profile entitled, "Ioflupane". |
| 26 | JZ | 401 | 3.6 | 8mm resolution requirement may need discussion | the collimator resolution requirement of <8mm should be discussed and aligned with manufacturer's recommendations for imaging of I123. It should also be specified that the resolution measurement should be done with I123. | We agree that spatial resolution measurements with I-123 is preferred. However, practically we believe that Tc-99m measurements would be easier to perform and be a reasonable indicator of I-123 resolution. The profile includes text that states that some collimators may not be adequate due to septal penetration. | No change to the current profile entitled, "Ioflupane". |
| 27 | JZ | 412 | 3.6 | the acquistion energy window is specified as 159 +/- 10%. Manufacturers may have different recommendations. Siemens e.g. recommends +/- 7.5% | please add: … or as recommended by the manufacturer; alternatively specify a range | Point well taken. | We have modified the profile to allow different energy windows when recommended by the manufacturer. |
| 28 | JZ | 320 | 3.3.2 | planar uniformity requirement needs to be more specific | add required counts and whether integral or differential uniformity | Planar uniformity is mentioned in section 3.3.2 and 4.2.1. We agree that details are needed and have added:                                                      Planar Uniformity (without collimator): At least every quater, detector response to I-123 should be assessed intrinsically following the guidelines of authoritative bodies such as ACR, IAEA, AAPM, NEMA, IPEM, IEC [Need to add these to reference list]. A flood image can be produced by suspending a small point source above the uncollimated gamma camera at a distance of five times the diameter of the crystal. Image count densities of at least 10,000 counts per pixel should be acquired (about 30 million total counts for a 64x64 matrix). The image should be visually assessed for variations in count density, noting any areas that clearly stand out. In addition, quantitative measurements of uniformity indices (such as coefficient of variation, integral uniformity and differential uniformity) defined in the above-mentioned guidelines should be carried out. Values should be recorded and compared with those obtained at acceptance and the action levels established at the time of acceptance testing. It is generally recommended that the coefficient of variation should be < 4%.                                 \n                                                                           System Uniformity (with collimator). Given that I-123 is an expensive product, the consistency of uniformity should be checked daily using either Tc-99m or Co-57 following the guidelines recommended by system manufacturers. For system uniformity measurements a flood source is placed in contact with the collimator face and 10 - 30 million total counts should be acquired. The image should be visually assessed for variations in count density. In addition, quantitative measurements of uniformity indices (such as coefficient of variation, integral uniformity and differential uniformity) should be carried out. Values should be recorded and compared with those obtained at acceptance and the action levels established at the time of acceptance testing. It is generally recommended that the coefficient of variation should be < 4%.\n | Profile text was expanded in section 4.2.1 as suggested to clarify the issue. |
| 29 | JZ | 320 | 3.3.2 | system spatial resolution of <8mm | should be cross checked with manufacturers collimator portfolios | We agree that this needed clarification and have now modified the text to specify that planar spatial resolution will be measured with Tc-99m as this is consistent with measurements that are available on manufacturer specifications. Such measreurements are also a reasonable surrogate for I-123 sptial resolution. | Changes have been made in 3.3.2, 3.6.2 and 4.2.2. |
| 30 | JZ | 320 | 3.3.2 | NaN | it should be clarified that this is a verification of COR, i.e. with corrections applied | We changed the text to state that this is a visual verification of the COR. We added text to section 4.2.3 on how to perform the COR verification (following NEMA guidelines). | Added new section 4.2.3. to follow NEMA guiidelines for CoR. |
| 31 | JZ | 700 | 4.2.3 | Quality Assurance procedures should be strengthened. | Consider increasing the length of the line profile, also COR is better tested with point sources | The 5 pixel recommendation was based on IAEA publication Quality Assurance for SPECT systems. We have replaced the 5 pixels with a band correponding to about 3 cm.  We have taken out the mention of COR measurement from here as COR measurement is previously discussed in the Table of Section 3.3.2 and added in a new section 4.2.3 describing CoR measurements with point sources. | Changes have been made to 4.2.4 (new) to change 5 pixels to 3cm. CoR with point sources has been descirbed in a new Section 4.2.3 |
| 32 | AB | NaN | Last Q/A in Open Issues (paragraph 790) | “Q. We cannot agree on a method for distinguishing the anterior from the posterior putamen, but we note that there are several software systems that do this. Their groundwork data and analyses are not available for vetting at this time. | GE DaTQuant semiautomatic processing fully matches the striatum to a 3D template built on a pairs of NM/MRI images. Each slice in the Striatum is used, with its own ROI, for the analysis in contrast to the written proposal which calls for using the sum of upper and lower slices and a single ROI. | Testing the analysis software will be possible using DRO data which will be provided via QIDW together with the true SBR values. Striatal phantom groundworks data (reconstructed and projection data) with true SBR will be also provided to interested parties via the same mechanism. | No change to the current profile entitled, "Ioflupane". |
| NaN | NaN | NaN | NaN | A. Enterprises claiming conformance based on distinctions between anterior and posterior putamen will need to describe their own methods and present their own evidence of qualification” | In order to compare the results of our method to the one proposed in the QIBA Profile, we are asking if QIBA can provide us with a set of studies with their SBR results. | Testing the analysis software will be possible using DRO data which will be provided via QIDW together with the true SBR values. Striatal phantom groundworks data (reconstructed and projection data) with true SBR will be also provided to interested parties via the same mechanism. | No change to the current profile entitled, "Ioflupane". |
| 33 | AB | 284 | NaN | “The use of gamma cameras with cadmium-zinc-telluride (CZT) detectors are currently beyond the scope of this profile” | Our new Discovery NM/CT 670 CZT system is being used for DaTScan acquisition showing favorable results. This is a large-field-of-view dual head system, with improved spatial and energy resolution . We are asking to reconsider the removal of the following clause “The use of gamma cameras with cadmium-zinc-telluride (CZT) detectors are currently beyond the scope of this profile” as we assume it was entered before this system was introduced. | On reflection, we agree that CZT systems should not be excluded if they meet the profile qualification criteria given that it should then meet the profiles claims. | Changes made to section 3.1 to include CZT systems. |
| NaN | NaN | NaN | NaN | NaN | We can share with QIBA DaTScan data acquired on this system if requested. | Would be happy to receive data from the CZT system | NaN |