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July 22, 2009

Regional Administrator
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

52-25430-01
03034704

52-25430-03
03036911

RE: Request for alternative test procedures for testing the dose calibrator and the disposal of Co-57 sources for all Nuclear Medicine Laboratories that I provide consulting services too.

Dear Sir or Madam:

Please find enclosed a copy of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM) national standard titled: "Minimum Quality Control Requirements for Nuclear Medicine Equipment". In this document, it states that the dose calibrator only requires the following tests (see pages 7 and 9):

Weekly	Yearly
Long term drift (constancy)	Long term drift (constancy)
Background and zero	Background and zero
	Accuracy

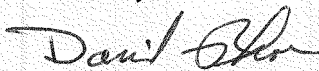
I would like permission to use the attached procedures regarding:

1. The annual testing for the dose calibrator and
2. Co-57 sealed source waste disposal.

My request is base on the increasing cost for radioactive sources, disposal and storage problems associated with Co-57 sources, and the increasing/current shortage of Tc-99m for nuclear medicine laboratories to treat patients. The attached procedures will be provided to all facilities.

If you have any questions, please feel free to contact me at 787-245-7248.

Sincerely,



David Rhoe

143962/143963
NRS/RGNI WATERALS-002

90-1-11-13

Dose Calibrator Testing Program

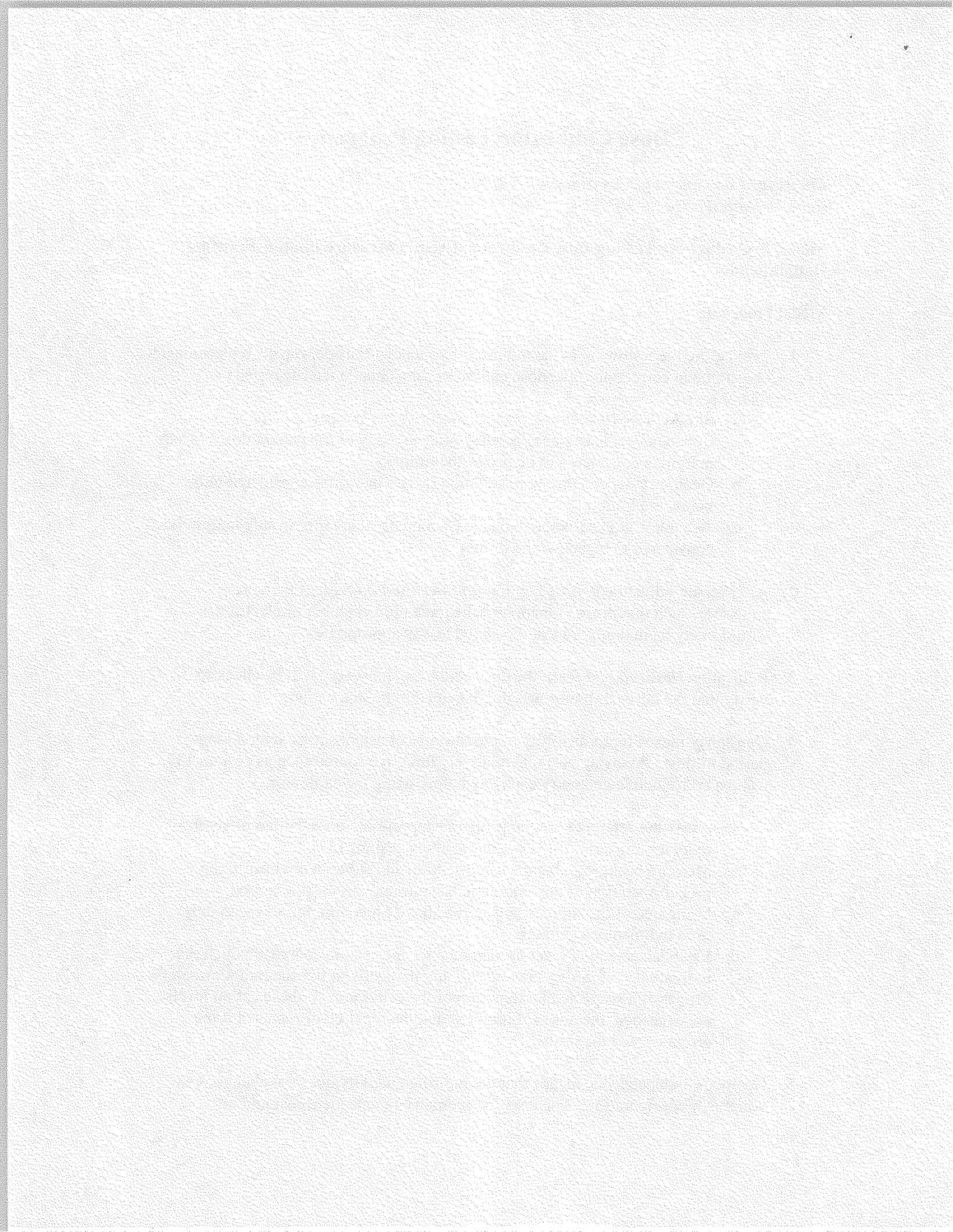
Limits for Constancy and Accuracy is +/- 10%

Remove from service +/- 10%

Model Procedure for Testing Dose Calibrator Used to Measure Photon-Emitting Radionuclide

Model Procedure

1. Test before the following at the indicated frequency (consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances):
 - a. Constancy, at least once each day prior to assay of the patient doses (a safe margin is considered to be below the limits).
 - b. Geometry dependence at installation (a safe margin is considered to be below the limits).
 - c. Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below the limits)
2. After repair, adjustment, or relocation (*greater than 20 feet*) of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above test as appropriate.
3. Relocation (*less than 20 feet*): the dose calibrator constancy will be check to verify that the dose calibrator was not damaged in the relocation.
4. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long live source such as cesium 137, using a reproducible geometry each day before using the calibrator.
 - a. Assay the reference source using the appropriate dose calibrator setting (e.g., use the cesium 137 setting to assay cesium 137).
 - b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background circuit if it is used.
 - c. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings.
 - d. Establish an action level or tolerance for the cesium source at which the individual performing the test will automatically notify the radiation safety officer of a suspected malfunction of the calibrator. If these action levels are exceeded, the dose calibrator should be repaired or replaced if the errors exceed the limits.
5. Geometry independence means that the indicated activity does not change with volume or configuration. The tests for geometry independence should be



conducted using syringes (and vials if bulb doses are received) that are representative of the entire range of shape, and size normally used.

Vial (only for bulk doses received)

- a. Place in a small vial between 1 to 10 mCi/ml.
- b. Assay the vial and record the volume and activity.
- c. Add to the vial 1 or 2 ml of saline or water, assay the vial and record the volume and activity.
- d. Repeat the process until the maximum volume has been assayed. The entire process must be completed within 10 minutes.

Syringe

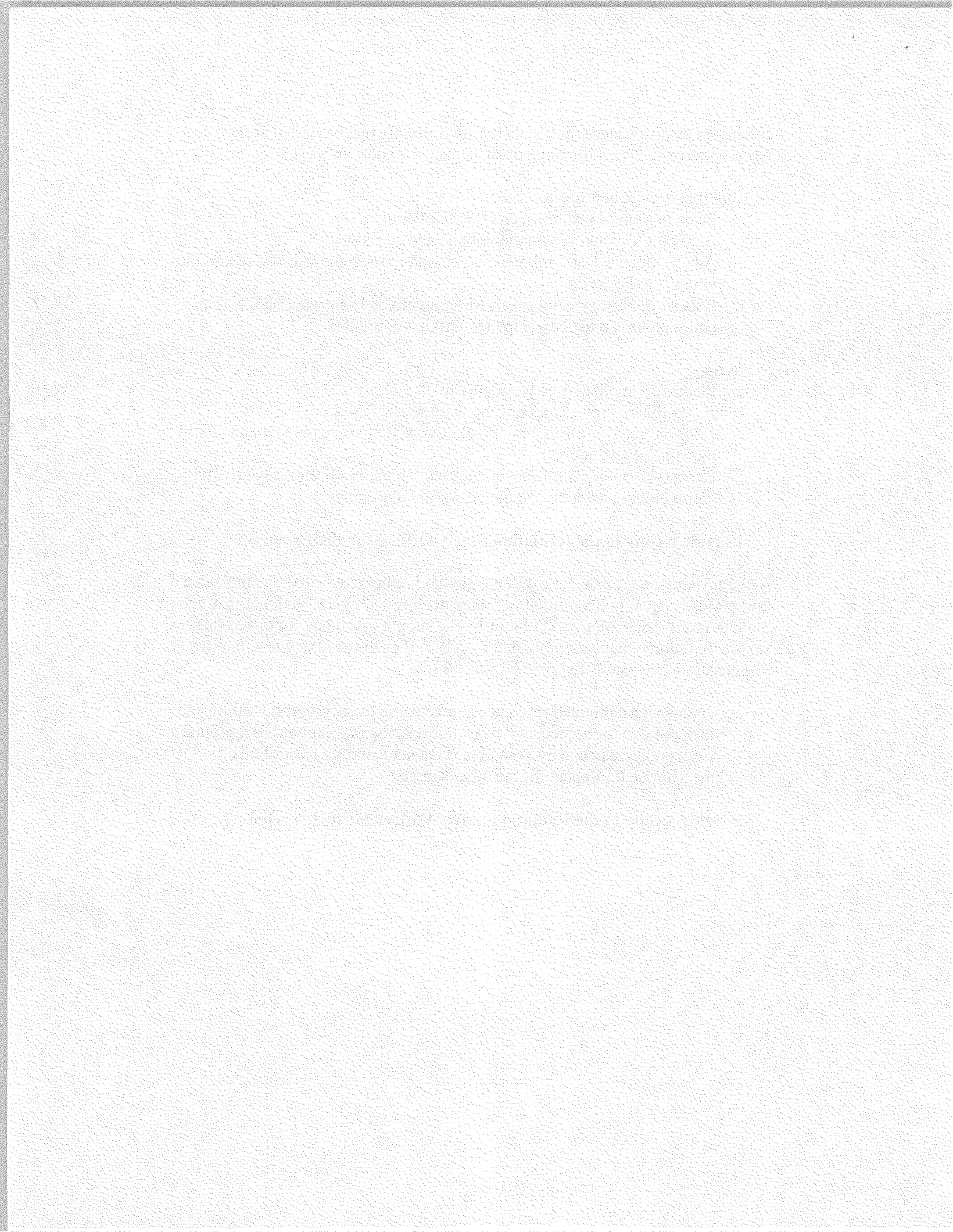
- a. Place in a small syringe between 1 to 10 mCi/ml.
- b. Assay the syringe and record the volume and activity.
- c. Add to the syringe 1 to 2 ml of saline or water, assay the vial and record the volume and activity.
- d. Repeat the process until the maximum volume has been assayed. The entire process must be completed within 10 minutes.

Provide a copy to the Radiation Safety Officer for their review.

6. Accuracy and means that, for a given calibrated reference source, the indicated millicuries is equal to the millicuries value determined by the National Institute of Standards and Technology (NIST) for by the supplier who has compared that source to a source that was calibrated by NIST. For the accuracy test, the two sources used are cesium 137, and barium 133.

- a. Assay each calibrated reference source using the appropriate setting and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for the other source.

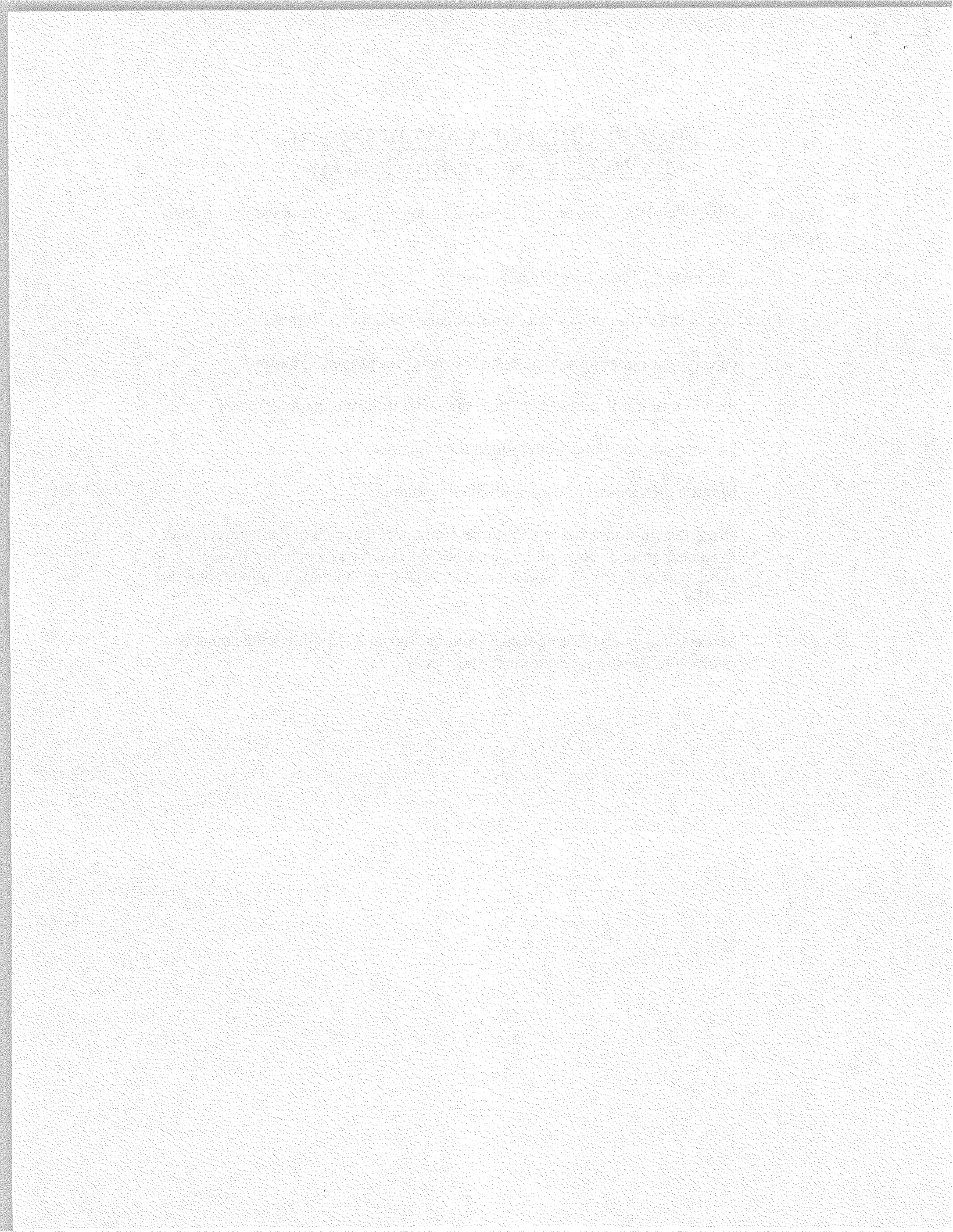
Provide a copy to the Radiation Safety Officer for their review.



PROCEDURE FOR-Co-57 DISPOSAL **BY DECAY-IN-STORAGE-(DIS)**

The physical half-life of Co-57 is approximately 271 days. Decay in storage is less than eight years.

1. Decay the material for at least 10 half-lives.
2. Prior to disposal as in-house waste, monitor each container as follows:
 - a. Check your radiation detection survey meter for proper operation;
 - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;
 - c. Remove any shielding from around the container;
 - d. Monitor all surfaces of each individual container;
 - e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the disposal date, and type of material (e.g., Co-57 check source or Co-57 flood source). Check to be sure no radiation labels are visible.
 - f. Sources that can be distinguished from background radiation levels must be returned to the storage area for further decay.



MINIMUM QUALITY CONTROL REQUIREMENTS FOR NUCLEAR MEDICINE EQUIPMENT

Prepared by the
Technical Standards Subcommittee
of the
Australian and New Zealand Society of Nuclear Medicine (ANZSNM)

Version 5.7 November 1999¹

All enquiries relating to this document should be directed, in the first instance, to:

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¹This document is periodically reviewed and updated by the ANZSNM Technical Standards Subcommittee and can be downloaded from the Society web site (<http://www.anzsnm.org.au>). **Please check that you have the latest version.**

Introduction

A minimum level of routine QC is required to ensure that nuclear medicine equipment is functioning properly. These minimum QC tests are intended to detect problems before they impact on clinical patient studies. They are not intended to provide a full evaluation of equipment performance. Further tests may be required to trace the cause of the problem and to ensure that the equipment is performing properly after service or adjustment.

These guidelines cover both gamma cameras as well as ancillary equipment such as dose calibrators and film processors. Exact QC procedures vary between manufacturers and models, thus it is impractical to provide detailed QC procedures covering all equipment. This document is thus divided into 3 parts:

Part A describes the aims and rationale of the recommended QC procedures. In particular, it attempts to provide background information on the reasons for performing particular procedures and the types of problems detected. An understanding of this is a prerequisite for implementing an effective QC program.

Part B provides recommendations on the frequency of the QC tests. As the frequency of tests depends on the equipment, criteria are provided for selecting appropriate test frequencies.

Part C gives general procedures for carrying out the recommended QC tests. These can be used as a basis for developing detailed protocols for individual makes and models of equipment. Recommended test equipment is also listed.

Additional useful and more specialised QC procedures are detailed in the appendix. It may be advisable in some instances, to include QC tests from this section in the routine QC program.

Practices are encouraged to call on the advice of experienced nuclear medicine physicists to draw up detailed QC protocols for their specific equipment based on the guidelines presented in this document.

It is imperative that QC procedures are carried out in a consistent manner (e.g. same collimator, orientation, activity, energy window width etc) and the QC results and settings are recorded. Proper record keeping greatly facilitates detection of gradual deterioration of performance over an extended period of time. A baseline set of QC results should be recorded after installation and acceptance testing to serve as a reference for the life of the equipment.

Part A - Description and Rationale of QC Tests

Gamma Cameras

Section 1 – Planar and SPECT Gamma Cameras

The following QC procedures apply to **both** planar and SPECT gamma cameras. Specific procedures for SPECT cameras only are given in section (2).

Visual Inspection

A visual inspection may reveal obvious defects which may compromise the safety or the imaging efficacy of the system (e.g. frayed or damaged electrical cables). Of particular importance is the visual inspection of collimators on a regular basis and whenever collimators are changed. Signs of denting or scratching may indicate mechanical damage to the collimator, and stains may be a sign of possible contamination. Both of these may produce artefacts such as cold or hot spots on planar images and rings on SPECT images.

Background Radiation Levels and Contamination

High levels of background radiation may arise from “hot” patients in the proximity of the imaging system or other sources of unshielded radiation. If high energy imaging agents are being used, the potential also exists for penetration through the back of the gamma camera, where shielding is thinner. Other sources of background radiation may include radioactive contamination on the floor, walls or even the detector itself. Background radiation, if it is of sufficient intensity, has the potential to seriously compromise any type of imaging. Even moderately elevated background levels have the potential to seriously degrade intrinsic uniformity or other intrinsic measurements.

Photopeak And Window Setting

Incorrect photopeak energy window setting(s) can degrade uniformity, reduce sensitivity or can increase the scatter contribution to the image. Particularly in older gamma cameras, the photopeak can change due to slight variations in high voltage, photomultiplier drift, changes in temperature and other factors.

Peak settings should be checked and adjusted in a consistent manner and the settings should be recorded to detect long term drift in the settings. Sudden changes in peak setting indicate a possible fault in the camera and should be fully investigated and rectified if necessary before the camera is again used for clinical studies.

It is important to check the energy window settings for all radionuclides used on a particular gamma camera as proper peak settings for one radionuclide (e.g. ^{99m}Tc) does not necessarily mean that the window settings for other radionuclides (e.g. ^{201}Tl and ^{67}Ga) are correct. In particular, if a change in the peak setting for one radionuclide is detected, it is likely that the settings for other radionuclides also need to be adjusted.

Uniformity

The uniformity or “flood” QC procedure checks that the response of the detector to a uniform irradiation is uniform within defined limits. It is one of the most basic QC tests of the gamma camera. Interpretation of clinical images taken with the gamma camera rely on the assumption that differences seen are due to differences in tracer distribution in the patient only and not differences introduced by the gamma camera.

A large number of possible problems in the gamma camera can degrade uniformity. It is thus a good general QC test of the proper performance of the camera. Uniformity defects can be quite marked and focal, such as during a failure of a photomultiplier tube, or there can be general degradation of uniformity across the field of view (FOV) due to inappropriate spatial linearity or energy corrections. Further QC tests may thus be required to detect the cause of the observed non-uniformities.

Uniformity can be checked either without collimator (intrinsic) or with collimator (extrinsic). Intrinsic uniformity is simpler to perform and does not require a flood tank or sheet source. However, it does not check for non-uniformities introduced by the collimators, which is particularly important for SPECT systems (see section 2). Further, on some multi-detector systems, it may not be easily possible to perform an intrinsic uniformity check.

To detect gradual deterioration in uniformity, it is important that uniformity measurements are carried out in a consistent manner (i.e. same orientation, same number of counts, same collimator if extrinsic etc) and records are kept to allow comparisons over periods of weeks or even months. Regular analysis of uniformity by a computer can facilitate detection of gradual deterioration prior to any visible change.

Uniformity can be different for different radionuclides and window settings. Thus it is important to ensure that uniformity is consistent for all radionuclides used on the gamma camera. Further, if non-standard or different window settings are introduced (e.g. narrow window, asymmetric window) their effect on uniformity should be assessed before clinical studies are performed.

Resolution

The purpose of resolution checks is to detect gradual, long term deterioration of resolution, rather than detecting abrupt changes. Inappropriate adjustments carried out during service may affect the resolution, without necessarily being apparent in the uniformity or other checks.

Multiple Window Spatial Registration

Multiple window spatial registration checks that images collected from different peaks of the same radionuclide (e.g. 93 keV and 184 keV peaks of ⁶⁷Ga) are spatially registered within a defined limit (typically better than 2 mm). Misregistration of the images will cause a deterioration of resolution, particularly towards the edge of the field of view. Again most problems which affect multiple window spatial registration will show up in other QC tests, such as uniformity. Inappropriate adjustment during service can cause excessive multiple window spatial misregistration without being apparent in the uniformity check.

Whole Body Scan Resolution

To avoid loss of resolution in the scanning direction during whole body scans, the relative physical position between bed and detector has to be accurately synchronised with the electronic offset applied to the image data to form the whole body image. Both mechanical problems and drift or inappropriate adjustment of image offset or size can cause a loss of resolution for whole body scans, particularly in older systems.

Section 2 – SPECT Cameras

QC procedures for SPECT cameras are in general more stringent, since the reconstruction process amplifies for instance non-uniformities in the planar projections. Corrections can be applied to SPECT data such as uniformity and centre of rotation offsets. Thus it is more important that the QC parameters are stable over time, rather than having an exact absolute value, to avoid the need for excessively frequent acquisition of corrections.

High Count Flood

Non-uniformities, particularly near the centre axis of rotation are substantially magnified by the filtered back projection reconstruction, resulting in ring artefacts. This places more stringent requirements on the uniformity of the camera. To achieve the required uniformity, flood correction is either applied on the fly during acquisition or post acquisition. To allow accurate measurement and correction of non-uniformities, the variation per pixel due to counting statistics has to be small. For a pixel coefficient of variation (COV) of <1% due to counting statistics, the count per pixel needs to be > 10,000. This requires a total count for a 64x64 matrix of 30 - 40 million counts and for a 128x128 matrix of 120 - 160 million counts. The COV or the number of counts required can be reduced somewhat by smoothing the data.

The same high count flood can typically be used to assess uniformity and act as the flood correction for SPECT data. Drifts in differential uniformity of >1% should be investigated and usually require collection of new uniformity corrections. However, uniformity corrections should not be used as a substitute for proper camera tuning and adjustment.

As collimators can also introduce non-uniformities, high count floods should be performed extrinsically with each collimator used for SPECT. It is important that the flood source used for extrinsic high count floods is uniform across the FOV and does not introduce non-uniformities. A long half-life sheet source (e.g. ^{57}Co sheet source) with guaranteed uniformity is thus preferred over fillable flood tanks.

Centre Of Rotation

The rotation axis (or centre of rotation) assumed by the reconstruction program has to accurately coincide with the mechanical axis of rotation to avoid loss of resolution and distortion in the reconstructed slices. Centre of rotation (COR) offsets are easily corrected during the reconstruction process. Thus it is more important that the centre of rotation offset is known and remains stable (<2 mm variation) for a period of at least a week.

Centre of rotation offset can vary with collimator and as a function of detector rotation and radius of rotation. It is important to establish which factors affect COR offset on each particular camera and then make appropriate allowances for it.

Section 3 – Correction Tables

Modern gamma cameras include on-line corrections for variations of energy response (photopeak) and linearity across the crystal. Some cameras also include on-line uniformity corrections. These corrections are designed to provide a uniform energy response and good linearity across the FOV which are also prerequisites for good uniformity.

As the camera slowly drifts over time, the correction tables have to be recollected to again apply proper correction factors during collection of the image. The exact frequency of reacquiring the correction tables depends on the stability of the camera. In general, energy and on-line uniformity corrections require more frequent updating than linearity correction tables. Thus energy and uniformity tables are usually collected by the operators, whereas linearity correction table collections are typically performed by the service engineers.

It should be stressed that energy and on-line uniformity corrections are designed for minor variations in response across the field of view. They are not a replacement for proper tuning of the gamma camera. While these corrections can in some instances correct for quite large non-uniformities, these should be corrected by having the camera retuned as they can affect linearity, resolution and overall sensitivity of the camera.

Other Equipment

Dose Calibrator

It is important that dose calibrators provide an accurate indication of the activity administered to the patient. For diagnostic studies, too large a dose will result in unnecessary radiation exposure to the patient, while a dose which is too low may prolong the study time or result in sub-optimal images. For therapy doses, it is even more important that the correct activity is administered to ensure that the therapeutic effect is achieved without excessive radiation burden to the patient.

Long Term Drift. To detect changes in calibration or malfunction of the dose calibrator, a source with a long half-life (e.g. ^{57}Co , ^{137}Cs) and known activity is measured and the displayed activity is compared with that predicted from the decay of the source. These sources can also be used to check drift of settings for clinically used radionuclides (e.g. $^{99\text{m}}\text{Tc}$, ^{201}Tl etc), by taking a baseline reading of

the long half-life sources on these settings when the dose calibrator is known to be accurately calibrated and then decay correcting these readings appropriately.

Background and Zero. Contamination in the chamber or drift in the electronics can result in a non-zero reading (positive or negative reading). If this is not checked and corrected, then measurements taken will be systematically either too high or too low. Contamination in the chamber or sample holder should be eliminated as much as possible and zero offsets and general background should be set to zero with the controls provided on most dose calibrators.

Accuracy. It is a requirement that the accuracy and calibration of the dose calibrator is traceable to the National Standard of activity measurement which is currently held by ANSTO. The Technical Standards Subcommittee of the ANZSNM conducts dose calibrator surveys every 1-2 years in which time calibrated sources, traceable to the national activity standard, are distributed to practices agreeing to take part. The sources include ^{99m}Tc , ^{131}I , ^{201}Tl and ^{67}Ga and provide a direct check of the accuracy of the dose calibrator for clinically used radionuclides. The accuracy of all dose calibrators in a practice should be checked at the time of the survey. Calibrated sources can also be specially ordered separate from the survey for checking dose calibrator calibration using sources other than those specified above (e.g. I-123), and for checking the dose calibrator after repair or if a malfunction is suspected.

Film Processor

Changes and contamination in the chemicals used for the film processor, changes in the temperature of the chemical and speed with which the film passes through the processor can affect the density of the image on the processed film.

Sensitometers are available to expose a calibrated grey scale wedge onto film, which is then processed normally. The density of the exposed wedge is then measured with a densitometer and compared to previous results to detect changes in the film processor. If a sensitometer is not available, the film can be exposed with a grey scale wedge or test pattern (e.g. SMPTE test pattern) displayed on a computer screen and again processed. The density of selected regions of the grey scale wedge are again measured with the densitometer and compared to the reference values. However, any drift detected with the computer generated grey scale can be due to either the film processor or the imager used or both and further tests would normally be required to pin point the cause of the drift.

Part B – Recommended Frequency of QC Tests

The recommended frequency of QC tests depends on the stability of particular equipment, automatic corrections performed etc. Thus it is important to tailor QC tests to particular equipment. Significant changes consistently detected between consecutive QC tests may require the frequency of the tests to be increased. Conversely, the frequency may be reduced if only minor fluctuations are detected over a series of QC results. Manufacturers' literature may also provide some guidance to the required frequency of tests. An experienced Nuclear Medicine Physicist may also provide advice on frequency for specific tests and equipment.

Tests such as uniformity, dose calibrator long term drift etc are specifically designed to detect malfunction of the equipment and sudden deterioration of performance before they affect a large number of patient studies. Thus the frequency of these tests should not be reduced even if their results remain consistent over a prolonged period of time.

The following schedule is thus recommended:

DAILY

Gamma Camera

- i. Visual Inspection
- ii. Background/Contamination Check
- iii. Photopeak check and adjustment, if necessary. Depending on the camera, this may require check and adjustment of photopeaks for all radionuclides used with the particular camera.
- iv. Uniformity check on gamma camera

Dose Calibrator

- i. Long term drift with long half-life source
- ii. Background and Zero

WEEKLY

Gamma Camera

High Count Flood uniformity check on computer, particularly for SPECT systems.

Film Processor

Grey scale test measurement.

SYSTEM DEPENDENT FREQUENCY

Gamma Camera

- i. Centre of Rotation
- ii. Energy and Uniformity Correction table collections for on-line corrections
- iii. Uniformity Correction floods for all collimators used for SPECT

AFTER MAJOR SERVICE

Gamma Camera

- i. Spatial Resolution
- ii. Uniformity with high count flood.
- iii. Multiple window spatial registration (recommended, but not essential and depends to some degree on the gamma camera)
- iv. Whole Body resolution (recommended, particularly for older systems, but not essential)

Film Processor

- i. Grey scale wedge

Dose Calibrator

- i. Long term drift source check
- ii. Background and zero check
- iii. Accuracy with a calibrated source (particularly recommended if the repairer does not provide evidence that the calibration of the dose calibrator has been checked with a traceable source post service or repair)

Part C - Description of QC Procedures

Due to the variations between equipment, no detailed description of the QC procedures can be given. The following are thus general guidelines for the QC procedures on which detailed, instrument specific QC tests can be based.

1 Recommended Equipment

The following is a list of recommended equipment to facilitate QC procedures. The list has been compiled to make QC measurements as simple as possible. In many cases, alternative devices or procedures can be used, but might be more laborious. It should also be noted that this list of equipment is only intended for routine QC and other equipment is required for full testing of the system, for example for acceptance testing.

Gamma Camera

- i. **Sheet Source:** ^{57}Co sheet source for high count extrinsic uniformity check and collection of uniformity correction floods. These are preferable over fillable flood tanks, since they avoid introduction of non-uniformities introduced by poor mixing, bulging, air bubbles etc in the fillable flood tanks. However, on some systems, a fillable flood tank may also be required to calibrate the system for non $^{99\text{m}}\text{Tc}$ radionuclides such as ^{67}Ga etc. Note however, that problems can occur when using a new ^{57}Co source due to impurities and/or too active a source.
- ii. **Resolution Phantom:** A 4 quadrant resolution phantom is recommended. The finest bars should be small enough to test the intrinsic resolution of the system (i.e. 2-2.2 mm bar width) and the largest bar should allow some extrinsic tests to be carried out (i.e. 4.5-4.8 mm bar width).
- iii. **COR Jig:** On some cameras, special jigs are required and supplied for calibrating COR offset and other calibration procedures. These should normally be supplied with the camera.

Dose Calibrator

- i. **Check Source:** Long half-life source (e.g. ^{57}Co , ^{137}Cs) with an activity of at least 40 MBq and preferably >200 MBq. A source with calibrated activity is preferred, but not essential.
- ii. **Calibration Source:** Supplied as part of dose calibrator survey for accuracy assessment or ordered for specific indications.

Film Processor

- i. **Densitometer:** Densitometer for measuring density of processed film. Small hand held densitometers are quite sufficient.
- ii. **Sensitometer:** Sensitometer to expose a standard grey scale wedge on the film. This is not essential provided a grey scale wedge can be exposed onto film from a computer screen.

Recommended Procedures

Gamma Camera and SPECT Systems

Daily Visual Inspection

A visual inspection of the collimators, should be performed daily and whenever collimators are changed. Signs of new dents, scratches or stains should be followed up with a background/contamination check and an extrinsic uniformity check before a suspect collimator is used for patient imaging. It should be borne in mind, however, that not all collimator damage may be externally visible.

A general visual inspection for any other defects which may compromise patient or staff safety (e.g. frayed or damaged electrical cables, mechanical faults in the camera or scanning table) should also be carried out on a daily basis. If any such defects are detected, the equipment should not be used until it is established that it is safe to do so.

Background/Contamination Checks

A background radiation check should be carried out with the collimator off, using the energy window which is most frequently used for imaging. The total number of counts acquired in a fixed time period and inspection of the energy spectrum will indicate the presence of any unusually high levels of background radiation. The measurement should be repeated with the camera head pointing towards the floor, ceiling and all four walls. A high reading in any particular direction may indicate background radiation from contamination (e.g. on the floor) or an unshielded source. A high reading which persists irrespective of the camera head orientation is indicative of contamination on the crystal face or the gamma camera head itself. Both of these conditions should be investigated and remedial action taken (e.g. decontamination or removal/shielding of the offending radiation source) before proceeding with any further checks or imaging.

The above background radiation checks should be repeated with the collimator on. This will check for possible contamination on the collimator itself. If such contamination is indicated, an extrinsic uniformity check should be carried out to assess the location of this contamination and its effect on uniformity. Decontamination of the collimator may be necessary before imaging can proceed.

Peaking

Peaking should preferably be performed intrinsically, to reduce scatter and ensure that an average peak for the whole FOV is obtained. If peaking is performed extrinsically, a sheet source must be used, to again ensure that an average peak for the whole detector is obtained.

Peaking should usually be performed at the same time as the uniformity check as the same set-up and source are used.

Intrinsic

- i. Suspend the source $> 4 \times$ FOV of the gamma camera away from the detector. The count rate should be between 10k cps and 30k cps.
- ii. Check for proper centring of the window on the photopeak and if necessary adjust the peak.
- iii. Record the peak setting in a log book and check for any large or gradual change from previous settings.
- iv. The peak should be checked for each radionuclide used on the camera for the day. This is particularly important if adjustment was required in step (ii).

Extrinsic

- i. Place the sheet source on the collimator. (If a fillable flood tank is used, protect collimator/detector from possible contamination with a protective cover).
- ii. Check for proper centring of the window on the photopeak and if necessary adjust the peak.
- iii. Record the peak setting in a log book and check for any large or gradual change from previous settings.
- iv. The peak should be checked for each radionuclide used on the camera for the day. This is particularly important if adjustment was required in step (ii).

Daily Uniformity Check

The daily uniformity check can either be performed intrinsically (without collimator) or extrinsically as follows:

Intrinsic

- i. Suspend a source (typically ^{99m}Tc) $> 4 \times$ FOV of the gamma camera away from the detector. The count rate should be between 10k cps and 30k cps.
- ii. Adjust pulse height analyzer window setting for proper peak.
- iii. Make sure that consistent set up is used (e.g. same distance of source, same orientation, peaking, same radionuclide, formatter settings etc) and that there is no significant background radiation from other sources.
- iv. Collect a uniformity image for at least 900k counts.
- v. Check for pronounced non-uniformity in image. Windowing may be used to highlight non-uniform areas if the study is collected on computer. Also compare with previous flood for any gradual degradation in uniformity.
- vi. File image (if acquired on film) or archive image (if collected on computer) for future comparison.

Extrinsic

- i. Place the sheet source on non attenuating supports approximately 10 cm in front of the collimator. (If a fillable flood tank is used, protect collimator/detector from possible contamination with a protective cover).
- ii. Adjust pulse height analyzer window for the proper peak of radionuclide being used.
- iii. Make sure that consistent set-up is used (i.e. same collimator, correction tables, orientation, peaking etc).
- iv. Collect a uniformity image for at least 900k counts.
- v. Check for pronounced non-uniformity in image. Windowing may be used to highlight non-uniform areas if the study is collected on computer. Also compare with previous flood for any gradual degradation in uniformity.
- vi. File image (if acquired on film) or archive image (if collected on computer) for future comparison.

Intrinsic Resolution

Intrinsic resolution test with 4 quadrant bar phantom.

- i. Place 4 quadrant bar phantom on detector.
- ii. Suspend a source $> 4 \times$ FOV of the gamma camera away from the detector. The count rate should be between 10k cps and 30k cps.
- iii. Make sure that consistent set up is used (e.g. same distance of source, same orientation, peaking, same radionuclide, formatter settings etc).
- iv. Collect an image of at least 900k on film. If a computer is connected to the camera, also collect an image on computer using at least a 256x256 matrix.
- v. Check for any degradation in resolution between previous images and the current resolution in the image.
- vi. File image (if acquired on film) or archive image (if collected on computer) for future comparison.

Multiple Window Spatial Registration

Place 4 quadrant bar phantom on detector.

- i. Suspend a source of ^{67}Ga > 4 x FOV of the gamma camera away from the detector. The count rate should be between 10k cps and 30k cps.
- ii. Peak the camera for ^{67}Ga setting windows over at least 2 peaks and preferably over all 3 peaks of ^{67}Ga .
- iii. Make sure that consistent set up is used (e.g. same distance of source, same orientation, peaking, formatter settings etc).
- iv. Collect an image of at least 900k on film. If a computer is connected to the camera, also collect image on computer using at least a 256x256 matrix.
- v. Check for any degradation in resolution between previous images and the current resolution image, particularly towards the edge of the FOV, where loss of resolution due to multiple window spatial registration is most apparent.
- vi. File image (if acquired on film) or archive image (if collected on computer) for future comparison.

Whole Body Scan Resolution

- i. Place the sheet source and 4 quadrant bar phantom on scanning bed such that the resolution phantom is between the sheet source and the collimator.
Resolution loss normally only occurs in the direction of scanning. Thus angle the phantom so that the bars are oriented at 45° to the direction of movement, to ensure that all bars measure to some extent in the direction of the motion.
- ii. Bring the collimator as close as possible to the resolution phantom while still allowing a whole body scan to be carried.
- iii. Make sure consistent set-up is used, same collimator (typically HRES or LEAP), the camera is peaked properly, etc
- iv. Collect whole body scan at a speed to give a total count of at least 500 k and preferably 900 k over the resolution phantom.
- v. Now collect a static image over the resolution phantom for the same number of counts.
- vi. Compare the two images. There should be no appreciable loss in the resolution of the whole body image compared to the static image.

High Count Flood

- i. The high count flood should be collected as recommended for your camera. Typically at least 30 million counts are required for a 64x64 matrix and 120 mil counts for a 128x128.
- ii. Routine system high count uniformity check should be performed with a consistent radionuclide / collimator combination. However, uniformity checks and flood correction tables should be set up for each collimator / radionuclide combination used on the camera for SPECT studies at a frequency dictated by the system stability and routine high count flood results.
- iii. Integral and differential uniformity should be calculated from the high count flood and recorded. The figures should be compared to previous results and a change of >1% should be investigated and rectified as necessary by for example collecting new correction tables.

Centre of Rotation

- i. Centre of rotation (COR) should be collected as specified by the manufacturer and recorded.
- ii. Large changes from previous values (>3 mm) and large changes in COR with rotation angle (> 1 mm) should be investigated and if necessary corrected.

Correction Tables

- i. Collect correction tables (e.g. energy) as per instructions for the camera and at the frequency recommended by the manufacturer.
- ii. If the frequency of collecting correction tables increases in order to maintain acceptable performance, a service and tuning of the equipment may be required or there may be a fault with the equipment.

Dose Calibrator

Background and Zero

- i. To check for contamination of the chamber, remove the sample holder and if possible the plastic well lining and observe any change in the reading. Any contamination should be removed. (*Note:* Never use the dose calibrator to measure sources without the plastic protective lining.)
- ii. Adjust background and zero settings for the dose calibrator as per manufacturer's instructions.

Long Term Drift

- i. Make sure the dose calibrator is properly zeroed and background is set to zero.
- ii. Place the check source in the dose calibrator. Make sure the same source position (i.e. same height in well etc) is used as the reading is affected by geometric factors.
- iii. Select the radionuclide preset used for the check source and take and record a reading. Take readings at all other presets for which initial calibration readings exist for your check source. Record the readings.
- iv. Compare the reading to that predicted from the decay of the check source. It should be within $\pm 5\%$ of the predicted reading. Larger discrepancies should be investigated and if necessary rectified.

Accuracy

- i. Assess the accuracy and reproducibility of the calibrator for all radionuclides supplied with the ANZSNM dose calibrator survey, and with other calibrated sources as required. The measured activity must be within $\pm 10\%$ of the stated activity (although $\pm 5\%$ should be achievable on most dose calibrators), and the results of 10 consecutive measurements on the same source must be within $\pm 5\%$ of the average. Inaccuracies of up to $\pm 20\%$ may be adjusted using the supplied sources as references. Major inaccuracies or losses of precision warrant service and proper investigation.

Film Processor

Grey Scale Wedge

Sensitometer Method

- i. Make sure that the processor has been switched on and warmed up for the required time as stipulated in the processor manual.
- ii. Expose two edges of the film with the grey scale wedge generated by the sensitometer in the dark room.
- iii. Make sure that the same light source is selected on the sensitometer and that the emulsion side of the film is always exposed.
- iv. Process the film normally.
- v. With the densitometer, measure the base level density (Base) of the film, the darkest (Dmax) area on the wedge and an intensity approximately in the middle of the scale and record the readings.
- vi. Compare the readings to previous and the reference readings. Changes in Base > 0.05 density units and Dmax > 0.1 density units should be investigated and rectified.

Computer Generated Grey Scale Method

- i. Make sure that the processor has been switched on and warmed up for the required time as stipulated in the processor manual.
- ii. Display a grey scale wedge with between 10-16 discrete steps from 0 to maximum brightness. Each step has to be large enough to be easily measurable by the densitometer. Test patterns such as the SMPTE pattern are suitable for this.
- iii. Make sure consistent window/threshold and grey scale and formatter settings are used.
- iv. Expose the grey scale pattern onto film and process film normally.
- v. With the densitometer, measure the base level density (Base) of the film, the darkest (Dmax) area on the wedge and an intensity approximately in the middle of the scale and record the readings.
- vi. Compare the readings to previous and the reference readings. Changes in Base > 0.05 density units and Dmax > 0.1 density units should be investigated and rectified.

Appendix – Optional and Special QC Tests

The following QC tests can be used to test aspects of the equipment more thoroughly, or may be required if the camera is used extensively for specific purposes. However, some of these tests may take considerable time to perform and require greater equipment resources (e.g. specialised phantoms) and expertise. They are most likely to be undertaken by a nuclear medicine physicist.

FWHM Resolution Measurement

The bar phantom used for the resolution tests above provides a quick method of checking resolution. However, interpretation is subjective, it may not detect minor changes in resolution and only gives semi-quantitative results.

Resolution is usually defined in terms of the Full Width at Half Maximum (FWHM) of a line spread function, that is, a profile is generated on the computer across the image of a line source and the full width of the profile at half the maximum level is found by either fitting a Gaussian function to the curve or measuring the width directly from the curve using linear interpolation between the curve points. To convert the FWHM measurement from units of pixels to units of mm, the pixel size has to be accurately known.

Intrinsic FWHM Measurement

To measure intrinsic FWHM resolution, a slit phantom is placed on the uncollimated detector. The slit phantom consists of 1 mm wide slits, 30 mm apart in a lead mask. A point source is placed >4 FOV from the detector (count rate should be 10k-30k cps) and an image is acquired.

NEMA specifications for measuring FWHM require a pixel size of $<(0.1 * \text{expected FWHM})$ i.e. for a camera with an intrinsic resolution of 3.5 mm, a pixel size of <0.35 mm is required. Thus, a large matrix size and/or large zoom are required to achieve the small pixel size. If this pixel size is difficult to achieve, meaningful results can still be obtained by using a pixel size of around 1 mm. In this case it is important that for each test, the same, consistent pixel size is used.

Profiles are generated across the image and FWHM is measured across the FOV. Programs are available on a number of gamma camera/computer systems which generate profiles and calculate mean, maximum and standard deviation of the FWHM automatically across the FOV.

Extrinsic FWHM Measurement

For extrinsic FWHM measurement, one or more line sources (line source diameter of 1 mm) are placed at the required distance from the collimator (e.g. at 10 cm). Images are then taken of the line source and profiles are generated and FWHM is calculated as above. The same comments regarding pixel size apply.

Pixel Size

Accurate calibration of pixel size is required for estimating size or volume or depth of organs, attenuation correction in SPECT reconstruction etc. On new equipment, accurate calibration of the pixel size is performed as part of the service and calibration of the camera or may be measured as part of other QC procedures such as COR measurement.

Note that it is useful to know pixel size for all acquisitions (e.g. zoomed) as filtering often is based on Nyquist frequency, which is dependent on pixel size ($f_n = \frac{1}{2a}$ where "a" is pixel size).

However, on older systems, particularly those connected to a separate computer, pixel size can change after service of the gamma camera or adjustment of the computer interface and should be checked regularly if studies are performed on the system which rely on proper calibration of pixel size for accurate results.

Pixel size can be calibrated with sources placed known distances apart or with slit or grid phantoms.

SPECT Resolution

For a proper operating SPECT system, the reconstructed resolution should be within 10% of the planar resolution at a distance from the collimator equal to the radius of rotation of the SPECT acquisition for a radius of rotation of 20 cm. Incorrect COR correction, mechanical misalignment and instability and problems with the reconstruction software can degrade the reconstructed SPECT resolution. Thus SPECT resolution measurement provides a good check of SPECT study quality.

To perform SPECT resolution measurement, a point or preferably line source is placed near the centre of and parallel to the axis of rotation. A SPECT study is then collected with sufficient counts to allow reconstruction with an unmodified ramp filter. The study is reconstructed and FWHM resolution is calculated for the slices spanning the source.

With the same source and collimator, at a distance equal to the radius of rotation of the SPECT study, a planar image is collected and the FWHM of the source in the planar images is calculated and compared with the resolution results from the SPECT study. The measured SPECT resolution should be within 10% of the planar image, if all components are operating correctly.

SPECT Total Performance Phantom

Phantoms such as the "Jaszczak" SPECT phantom are designed to provide an evaluation of overall performance of the SPECT system. They contain a uniform section for detecting ring artefacts, cold spheres of varying sizes for assessing contrast and cold and/or hot rods.

The phantoms are typically filled with 400-600 MBq of ^{99m}Tc and images are collected over 30 min or more to obtain a very high count SPECT acquisition. This does not reflect clinical conditions, but is designed to demonstrate the limit of the performance of the SPECT system.

These phantoms are particularly useful for detecting slow overall degradation of the SPECT performance. However, this requires that a reference study with the phantom is performed when the SPECT system is known to be working optimally e.g. during acceptance testing. Subsequent phantom studies are then performed under the same condition and compared to the reference study to detect changes in performance. These studies are also useful to check the proper functioning of SPECT acquisition and reconstruction software after major software upgrades.

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There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

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