NYSDOH ELAP RADIOCHEMISTRY CHECKLIST

This checklist incorporates references to both 'The NELAC Institute' 2003 and 2009 Standards, **where applicable**. The 2009 reference is in brackets.

Directions: Place a mark (e.g., /, √ or X) in the appropriate column (Yes (Y), No (N), or Not Applicable (NA)). If it is an observation on areas for possible improvement, place a mark under the Suggestion (S) column. In database, use code "SGST."

Lab ID: _____ Assessment ID: _____

Lab Name: _____

If the information on the "**Lab Pre-Assessment Report**" is **NOT** accurate, note the changes that need to be made below. In addition, the lab will need to formally request the change using Application Form 107.

Address (Mailing): _____

Address (Physical Location):
_____

Telephone: _____

E-mail: _____

Personnel Interviewed:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

At the time of the assessment, a question marked 'yes' indicates that no evidence of a deficiency was observed.

Assessment Date(s):_____ Assessor (Signature): _____

If this was a team assessment, indicate the Lead Assessor's name. _____

Radiochemical Analysis Detailed Method Review	Deficiency Code	Comments
Method Number: **SOP Number:** **Rev.:** **SOP date:** **Personnel records observed:** **Data records observed:**		
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Relevant Aspect of Standards	NELAC Reference [2009]	Y	N	N/A	S	Codes	Comments
Does the laboratory demonstrate that it meets all requirements contained in a mandated test method or by regulation, even if the requirement is more stringent than the corresponding standard? Note: If it is unclear which requirements are more stringent, the standard from the method of regulation shall be followed)	D. 5.1.1 [M2,5.9.3(c)]					**000d41** or **000d11**	
Are the quality control protocols specified by the laboratory's method manual followed by all analysts?	D [M2,5.9.3(c)]					**000d42**	
Are all essential quality control measures incorporated in the lab's method manual?	D [M2,5.9.3(c)]					**000d43**	
Are all quality control measures assessed and evaluated on an on-going basis and is quality control acceptance criteria used to determine the validity of the data?	D [M2,5.9.3(b)]					**000d44**	
Does the laboratory have procedures for developing acceptance/rejection criteria for each test method where no method or regulatory criteria exists?	D [M2,5.9.3(c)]					**000d45**	
Are method blanks, analyzed at a frequency of one per preparation batch, used to assess batch acceptance?	D.4.1.a.1 [M6,1.7.2.1(a-b)]					**00d410**	
Is the method blank result assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.1.a.1 [[M6,1.7.3.1(a)]					**0d410a**	
When the method blank acceptance criteria are not met, are the corrective action and contingencies specified in the laboratory method manual followed and are results reported with appropriate qualifying codes?	D.4.1.a.1 [M6,1.7.3.1(a) & (c)]					**0d410b**	
Does the laboratory note the occurrence of a failed method blank and the actions taken in the laboratory report?	D4.1.a.1 [M6,1.7.3.1(d)]					**0d410c**	
In the case of gamma spectrometry, is the method blank prepared from a similar counting geometry that is empty or filled to similar volume with ASTM Type II water used to partially simulate gamma attenuation due to a sample matrix?	D.4.1.a.2					**00d411**	
Is there no subtraction of the required method blank result from the sample results in the associated preparation or analytical batch, unless permitted by the test method or program?	D.4.1.a.3 [M6,1.7.2.1(c)]					**00d412**	
If a correction factor such as instrument background, analyte presence in tracer, reagent impurity, peak overlap or calibration blank is applied, is it applied to all analyzed samples and internal QC samples?	D.4.1.a.3 [M6,1.7.2.1(c)]					**00d413**	
Is the method blank prepared with similar aliquot size to that of the routine	D.4.1.a.4					**0d413a**	

Relevant Aspect of Standards	NELAC Reference [2009]	Y	N	N/A	S	Codes	Comments
samples for analysis?	[M6,1.7.2.1(c)]						
Are the method blank result and acceptance criteria calculated in a manner that compensates for sample results based upon differing aliquot size?	D.4.1.a.4 [M6,1.7.3.1(b)]					**00d414**	
Is a Laboratory Control Samples (LCS) analyzed at a frequency of one per preparation batch?	D.4.1.b.1 [M6,1.7.2.2(b)]					**00d415**	
Are the results of the analysis of the LCS used as one of the quality control measures to be used to assess batch acceptance?	D.4.1.b.1 [M6,1.7.4.2(a)]					**00d416**	
Is the laboratory control sample result assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.1.b.1 [M6,1.7.3.2(b)]					**00d417**	
When the specified laboratory control sample acceptance criteria is not met, are the specified corrective action and contingencies followed?	D.4.1.b.1 [M6,1.7.3.2(c)]					**00d418**	
Is the occurrence of a failed laboratory control sample acceptance criteria and the actions taken noted in the laboratory report?	D.4.1.b.1 [M6,1.7.3.2(d)]					**00d419+**	
Is a Matrix Spike analyzed at a frequency of one per preparation batch for those methods which do not utilize an internal standard or carrier and for which there is a physical or chemical separation process and where there is sufficient sample to do so? (Note: the exceptions are gross alpha, gross beta, and tritium which require matrix spikes for aqueous samples.)	D.4.1.b.2					**00d420**	
Are the results of the analysis of the matrix spike one of the quality control measures used to assess batch acceptance?	D.4.1.b.2 [M6,1.7.3.3(a)(i)]					**00d421**	
Is the matrix spike result assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.1.b.2 [M6,1.7.3.3(a)(ii)]					**00d422**	
When the specified matrix spike acceptance criteria is not met, are the specified corrective action and contingencies followed?	D.4.1.b.2 [M6,1.7.3.3(a)(ii)]					**00d423**	
Is the occurrence of a failed matrix spike acceptance criteria and the actions taken noted in the laboratory report?	D.4.1.b.2 [M6,1.7.3.3(a)(iii)]					**00d424**	
Is the lack of sufficient sample aliquot size to perform a matrix spike analysis noted in the laboratory report?	D.4.1.b.2 [M6,1.7.2.3(a)(iv]					**00d425**	
Is the activity of the laboratory control sample (1) at least ten (10) times the detection limit and (2) at a level comparable to that of routine samples if the sample activities are expected to exceed ten (10) times the detection limit? Note: In 2003 NELAC Standard, the activity of the LCS at least 5 times the MDL and at a level comparable to routine samples if activity is to exceed 5 times the	D.4.1.b.3 [M6,1.7.2.2(e)]					**00d426**	

Relevant Aspect of Standards	NELAC Reference [2009]	Y	N	N/A	S	Codes	Comments
MDL.							
Is the activity of the matrix spike analyte(s) greater than ten times the detection limit?	D.4.1.b.4 [M6,1.7.2.3(a)(v)]					**0d426a**	
Are the laboratory standards used to prepare the LCS and matrix spike from a source independent of the laboratory standards (and meeting the requirements for reference standards per D.4.7.a) used for instrument calibration?	D.4.1.b.5 [M6,1.7.2.2(f)] [M6,1.7.2.3(a)(vi)]					**00d427**	
When a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g. isotopic uranium: U-234, -235, and -238), is one of the analyte isotopes included in the laboratory control or matrix spike sample at the indicated activity level?	D.4.1.b.6 [M6,1.7.2.2(g)]					**00d428**	
Is the matrix spike prepared by adding a known activity of target analyte after sub sampling, if required, but before any chemical treatment (e.g. chemical digestion, dissolution, separation, etc).	D.4.1.b.6 [M6,1.7.2.3(a)(vii)]					**00d428a**	
Where more than one analyte isotope is present in the LCS or matrix spike is above the specified detection limit, is the activity level of each analyte assessed against the specified acceptance criteria?	D.4.1.b.6 [M6,1.7.2.2(g)]					**00d429**	
Where gamma spectrometry is used to identify and quantitate more than one analyte isotope, does the LCS and matrix spike contain isotopes that represent the low (e.g. americium-241), medium (e.g. cesium-137) and high (e.g. cobalt-60) energy range of the analyzed gamma spectra? (The isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.)	D.4.1.b.7 [M6,1.7.2.2(h)]					**00d430**	
Is the LCS prepared using a similar aliquot size to that of the routine samples for analysis?	D.4.1.b.8 [M6,1.7.2.2(i)]					**0d430a**	
Are replicates analyzed at a frequency of one per preparation batch where there is sufficient sample to do so?	D.4.2.a [M6,1.7.2.3(b)]					**00d431**	
Are the results of replicate analysis one of the quality control measures used to assess batch acceptance?	D.4.2.a [M6,1.7.2.3(b)]					**00d432**	
Is the replicate result assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.2.a [M6,1.7.3.3(b)(iii)]					**00d433**	
When the specified replicate acceptance criteria is not met, are the specified corrective action and contingencies followed?	D.4.2.a [M6,1.7.3.3(b)(iii)]					**00d434**	
Does the corrective action take into consideration sample inhomogeneity which may be a cause of the failed replicate acceptance criteria?	D.4.2.a [M6,1.7.3.3]					**0d434a**	

Relevant Aspect of Standards	NELAC Reference [2009]	Y	N	N/A	S	Codes	Comments
Is the occurrence of a failed replicate acceptance criteria and the actions noted in the laboratory report?	D.4.2.a [M6,1.7.3.3(b)(iv]					**00d435**	
For low level samples (less than approximately three times the detection limit), does the laboratory analyze duplicate LCS's or a replicate MS to determine reproducibility within a preparation batch?	D.4.2.b [M6,1.7.2.3(b)(iv)]					**0d435a**	
For those methods that utilize a tracer (i.e. internal standard), is each sample result associated tracer recovery calculated and reported?	D.4.1.c.1 [M6,1.7.2.3(c)]					**00d436**	
Is the tracer added to the sample after sub sampling, if required, but before any chemical treatment (e.g. chemical digestion, dissolution, separation, etc) unless otherwise specified by the method.	D.4.1.c.1 [M6,1.7.2.3(c)]					**00d436a**	
Is the tracer recovery for each sample results one of the quality control measures used to assess the associated sample result acceptance?	D.4.1.c.1 [M6,1.7.2.3(c)]					**00d437**	
Is the tracer recovery assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.1.c.1 [M6,1.7.2.3(c)]					**00d438**	
When the specified tracer recovery acceptance criteria is not met, are the specified corrective action and contingencies followed?	D.4.1.c.1 [M6,1.7.2.3(c)]					**00d439**	
Is the occurrence of a failed tracer recovery acceptance criteria and the actions taken noted in the laboratory report?	D.4.1.c.1 [M6,1.7.2.3(c)]					**00d440**	
For those methods that utilize a carrier (i.e. internal standard), is each sample associated carrier recovery calculated and reported?	D.4.1.c.2 [M6,1.7.2.3(d)]					**00d441**	
Is the carrier added to the sample after sub sampling, if required, but before any chemical treatment (e.g. chemical digestion, dissolution, separation, etc) unless otherwise specified by the method.	D.4.1.c.2 [M6,1.7.2.3(d)]					**00d441a**	
Is the carrier recovery for each sample one of the quality control measures used to assess the associated sample result acceptance?	D.4.1.c.2 [M6,1.7.2.3(d)]					**00d442**	
Is the carrier recovery assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.1.c.2 [M6,1.7.2.3(d)]					**00d443**	
When the specified carrier recovery acceptance criteria is not met, is the specified corrective action and contingencies followed?	D.4.1.c.2 [M6,1.7.2.3(d)]					**00d444**	
Is the occurrence of a failed carrier recovery acceptance criteria and the actions taken noted in the laboratory report?	D.4.1.c.2 [M6,1.7.2.3(d)]					**00d445**	
Is the Initial Demonstration performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel or method?	D.4.3.a [M6,1.6.1]					**00d446**	
Does the laboratory use the results of proficiency test sample analysis to evaluate	D.4.3.b					**00d446a**	

Relevant Aspect of Standards	NELAC Reference [2009]	Y	N	N/A	S	Codes	Comments
its ability to produce accurate data?							
Does the laboratory calibrate radiochemistry analytical instruments a.__ prior to initial use, b.__ after they are placed back into service after malfunction, c.__ with change in response as determined by a performance check, and d.__ when response exceeds predetermined acceptance criteria for instrument quality control?	D.4.4.a.1 [M6,1.7.1(a)]					**0d459a** **0d459b** **0d459c** **0d459d**	
Do the standards have the same general characteristics (i.e. geometry, homogeneity, density, etc.) as the associated samples?	D.4.4.a.2 [M6,1.7.1(a)]					**00d460**	
Does the laboratory perform instrument calibrations with appropriate reference standards? Note: "Appropriate" means meeting the requirement in NELAC 2003 Section D4.7(a) and TNI 2009 Section 1.7.2.5(c).	D.4.4.a.2 [M6,1.7.1(a)]					**00d460a**	
Is the frequency of calibration addressed in the laboratory method manual if not addressed in the method?	D.4.4.a.3 [M6,1.7.1(a)]					**00d461**	
Is a specific frequency of calibration (e.g. monthly) or are observations from the associated control or tolerance chart used as the basis for calibration specified?	D.4.4.a.3 [M6,1.7.1(a)]					**00d462**	
Are instrument performance checks using appropriate check sources performed on a regular basis and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the calibration has not changed?	D.4.4.b [M6,1.7.1(b)]					**00d475**	
Is the same check source used in the preparation of the tolerance chart or control chart at the time of calibration used in the performance checks of the instrument?	D.4.4.b [M6,1.7.1(b)]					**00d476**	
Does the check sources provide adequate counting statistics for a relatively short count time?	D.4.4.b [M6,1.7.1(b)]					**00d477**	
Is the check source sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel?	D.4.4.b [M6,1.7.1(b)]					**00d478**	
For alpha and gamma spectroscopy systems, do the instrument calibration verification checks include checks on the counting efficiency and the relationship between channel number and alpha or gamma ray energy?	D.4.4.b [M6,1.7.1(b)]					**00d479**	
For gamma spectroscopy systems, are the calibration verification checks for efficiency and energy calibration performed on a day of use basis along with performance checks on peak resolution?	D.4.4.b.1 [M6,1.7.1(b)(i)]					**00d480**	
For alpha spectroscopy systems, are the calibration verification checks for energy	D.4.4.b.2					**00d481**	

Relevant Aspect of Standards	NELAC Reference [2009]	Y	N	N/A	S	Codes	Comments
calibration performed on **weekly** basis and the performance check for counting efficiency shall be performed on at least a **monthly** basis?	[M6,1.7.1(b)(ii)]						
For gas-proportional and scintillation counters, is the calibration verification checks for counting efficiency performed on a day of use basis?	D.4.4.b.3 [M6,1.7.1(b)(iii)]					**00d482**	
For batches of samples that uninterruptedly count for more than a day, is a performance check performed at the beginning and end of the batch as long as this time interval is no greater than one week?	D.4.4.b.3 [M6,1.7.1(b)(iii)]					**0d44b3**	
For scintillation counter, is the calibration verification check for counting efficiency performed on a day of use basis?	D.4.4.b.4 [M6,1.7.1(b)(iv)]					**00d483**	
Are background calibration measurements made on a regular basis?	D.4.4.c [M6,1.7.1(c)]					**00d453**	
Are background calibration measurements monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required data quality objectives	D.4.4.c [M6,1.7.1(c)]					**00d454**	
Are background calibration measurements subtracted from the total measured activity in the determination of the sample activity?	D.4.4.c [M6,1.7.1(c)]					**00d455**	
For gamma spectroscopy systems, are background calibration measurements performed on at least a monthly basis?	D.4.4.c.1 [M6,1.7.1(c)(i)]					**00d456**	
For alpha spectroscopy systems, are background calibration measurements performed on at least a monthly basis?	D.4.4.c.2 [M6,1.7.1(c)(ii)]					**00d457**	
For gas-proportional counters, are background measurements performed on a weekly basis?	D.4.4.c.3 [M6,1.7.1(c)(iii)]					**0d457a**	
For scintillation counters, are background calibration measurements performed on a day of use basis?	D.4.4.c.4 [M6,1.7.1(c)(iv)]					**00d458**	
Are the detection limits determined prior to sample analysis and redetermined each time there is a significant change in the test method or instrument type?	D.4.5.a [M6,1.5.2.1(b)] [M6,1.5.2.1(c)]					**0d458a**	
Are the procedures for the determination of detection limits documented and consistent with mandated methods or regulations?	D.4.5.b [M6,1.5.2]					**0d458b**	
Are the procedures for data reduction consistent with this standard?	D.4.6.a [M6,1.7.2.4]					**0d458c**	
Does the laboratory have written procedures for monitoring radiation measurement instrumentation for radioactive contamination?	D.4.4.d [M6,1.7.1(d)]					**0d458d**	
Do these procedures for monitoring radioactive contamination indicate the	D.4.4.d					**0d458e**	

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frequency of the monitoring and include criteria that initiate corrective action?	[M6,1.7.1(d)]						
Is each result reported with an associated measurement uncertainty, and are the procedures for determining measurement uncertainty documented and consistent with mandated methods and regulations?	D.4.6.b [M6,1.7.2.4(b-c)]					**00d463**	
Does the laboratory's quality control program establish and maintain provisions for radio nuclide standards?	D.4.7.a [M6,1.7.2.5(c)]					**00d465**	
Are the reference standards that are used obtained from the National Institute of Standards and Technology (NIST), EPA, or suppliers who participate in supplying NIST standards or NIST traceable radionuclides?	D.4.7.a.1 [M6,1.7.2.5(c)(i)]					**00d466**	
Are any reference standards purchased outside the United States traceable back to each country's national standards laboratory?	D.4.7.a.1 [M6,1.7.2.5(c)(i)]					**00d467**	
Do commercial suppliers of reference standards conform to ANSI N42.22 to assure the quality of their products?	D.4.7.a.1 [M6,1.7.2.5(c)(i)]					**00d468**	
Are reference standards accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates?	D.4.7.a.2 [M6,1.7.2.5(c)(ii)]					**00d469**	
Does the laboratory consult with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value?	D.4.7.a.3 [M6,1.7.2.5(c)(iii)]					**00d470**	
Does the laboratory does not use a value for a standard other than the decay corrected certified value?	D.4.7.a.3 [M6,1.7.2.5(c)(iii)]					**00d471**	
Does the laboratory have written procedures for handling, storing and establishment of expiration dates for reference standards?	D.4.7.a.3 [M6,1.7.2.5(c)(iii)]					**00d471a**	
Are all reagents used analytical reagent grade or better?	D.4.7.b [M6,1.7.2.5(a)]					**00d472**	
Does the laboratory establish written procedures to minimize the possibility of cross-contamination between samples?	D.6.9 [M3,1.7.8.2]					**00d473**	
Does the laboratory maintain a radiological control program that addresses analytical radiological control?	D.4.8 [M6,1.7.2.7(c)]					**00d474**	
Does the program address the procedures for segregating samples with potentially widely varying levels of radioactivity?	D.4.8 [M6,1.7.2.7(c)]					**00d484**	
Does the radiological control program explicitly define how low level and high level samples will be identified, segregated and processed in order to prevent sample cross-contamination?	D.4.8 [M6,1.7.2.7(c)]					**00d485**	
Does the radiological control program include the measure taken to monitor and	D.4.8					**00d486**	

Relevant Aspect of Standards	NELAC Reference [2009]	Y	N	N/A	S	Codes	Comments
evaluate background activity or contamination on an ongoing basis?	[M6,1.7.2.7(c)]						