

**Radiochemistry Expert Committee (REC)
Meeting Summary**

September 27, 2017

1. Roll Call and Minutes:

Bob Shannon, Chair, called the meeting to order at 1:00 pm Eastern on September 27, 2017 by teleconference. Attendance is recorded in Attachment A – there were 7 members present. Associates: Jim Chambers, Carl Kircher, Brian Miller, Terry Romanko, Bill Ray and Carolyn Wong.

Meeting minutes are distributed by email for comment/revision for a week and then posted on the TNI website.

2. Small Laboratory Handbook

It is complete and has been sent to Ilona.

Bob noted that after the committee voted last time, he made one editorial change. Keith had language about combined standard deviation and it should have been combined uncertainty. It was corrected. No one objected to the change.

The committee will wait for any additional feedback from the Quality System Expert Committee. Bob thanked Dave for all his hard work on this document!

3. Training for ABs in Albuquerque on January 25th AM

Jerry asked if the committee would be interested in doing some assessor/evaluator Radiochemistry training at the meeting. Bob has lots of training he has done that he can dust off. It would need some fine-tuning, but the committee would not have to start at zero. It could be 4 hours of training on Thursday.

Bob has modules about DW methods and how they work. Bob thinks the stuff he has will need to be updated with how it relates to Module 6 of the TNI Standard. He could put a data package together for people to work with. He has lots of methods.

Jim Chambers noted that DOECAP (DoE Consolidated Audit Program) is moving towards AB assessors reviewing for DoE/DoD QSM. A lot of the new assessors need training. He feels it needs to be opened up beyond just water. There are 3 assessors under DOECAP that will want to take this training.

Ilona talked about the possibilities of using a Webinar or Recorded Webcast. Need to

look at what is planned to decide how best to proceed. If it is recorded and a data package review is a group exercise, the committee will need to think about how to do this with a webcast.

Marty noted training ABs is dependent on experience too. Bob said they would talk about what they can expect in the field. Perhaps do some mock interviews?

Bob and Carolyn had talked previously. She would like to see more interactive training. They would both like to see the training go beyond DW. There will need to be a test in the end, similar in format what WET did with their course.

The interactive training can be based on some materials Bob currently has. People look at information and talk about what is there, what isn't, etc ... They can also do mock interviews.

Carl Kircher may be willing to help with this class. Marty would be willing to help too.

Bob asked if labs can look for a data package – examples. He asked if TestAmerica can help. Larry can help provide data, but can't help with training. Larry will work with Terry. Bob will need to decide what example data he needs. Radium-228 is probably a good example. Yoon may also be able to provide some data, but will need to check. Her data would show an alternative method - Radium 226/228 by gamma spec.

Summary of training discussion:

- DOECAP needs training that goes beyond water
- Within 14 months - possibly get cross training for DOECAP
- There will be 3 potential ABs for DOECAP/DOD
- Will there be a charge for the training?
- Ilona says there may a charge that will not be excessive – no details yet
- Do as a webinar or as a webcast?
- If done as a webcast, would likely provide additional supporting information for people who are not live / on-site – what kind of support would be needed
- Will probably need to have a test at the end
- Carolyn – suggested interactive training
- Volunteers
- Carl – was involved in 2007 – would be willing to be involved
- Marty will help as time permits
- Yoon – Ra-226/228 by gamma spec
- Sample data could be obtained from TestAmerica
- Larry can get from SL and Richland
- Possibly use Ra-228 as an example.

The committee decided that they would like to provide this training in Albuquerque in January 2018. It will be a 4 hour training. Bob would prefer not to do a Webinar ... only a webcast. We can continue with this training at other meetings. Change the primary measurement technique at each meeting. Bob will let Jerry know that the committee will be doing the training.

4. Status on TNI PT Acceptance Criteria SOP

Vas, Keith and Bob have been working on this together. A document was sent by email (date) summarizing where they are.

Keith – The goal was to extend the scope beyond DW and to avoid the bias acceptance ranges that would discourage labs from correcting problems. Use performance based approach instead of just historical. He noted that the limits are different depending on what they do. How do you determine the upper and lower ends of the testing. Need to get through the conceptual issues first and can then go back into the details.

Carl was the original author of the PT approach, so this topic is of great interest to him. Carl supports extending beyond just DW. He asked if the DW can be extrapolated from Non-Potable Water (NPW).

Bill Ray noted that for wastewater analysis, they use same criteria as DW. CA is looking at converting WW to DW.

Keith provided some thoughts on Radiochemistry FoPT limits and how they are developed by email. There was quite a bit of correspondence on the topic and all of this is captured in Attachment D. The reader should start at the bottom of the email chain.

Keith noted that one option is to use laboratory limits. Carl noted that a lot of laboratory acceptance limits are getting wider and wider. Bob noted that some labs may want to use tighter limits because they can show their limits are tighter. This might not be an issue. Carl is still concerned that the market may not be a quality based market.

Carl also noted that expanding PTs beyond DW probably needs an ARA (Analyte Request Application). He would be happy to sponsor a request to expand the Radiochemistry PTs. Ilona explained how the committee can review the process for adding analytes that are not currently on FoPT tables. Ilona forwarded the SOP for this process to Bob.

Carl offered to provide Keith with data that has been masked. He noted that the Chemistry FoPT Subcommittee has an SOP that outlines how Radiochemistry limits are currently calculated. A copy of this SOP was sent to the Radiochemistry Expert Committee by the PT Program SOP Subcommittee for review and update. The Radiochemistry Expert Committee wants to expedite this process and hopes it will be considered as limits are being updated.

Brian (ERA) has had a lot of requests for NPW Radiochemistry PTs.

Tom and Keith exchanged some emails on the formulas (Attachment D). Tom now agrees with Keith's comments and the model does have to be simple. Keith thought like Tom did, but in the end he felt a linear model was actually the better way to go. It is consistent with what has been done, but the committee would probably propose a different way of calculating the 2 parameters for it. Carl confirmed that what he read is similar to what is currently being done.

The job is easier since the equation is the same.

Carl noted that there are some PTPEC and Chemistry FoPT Subcommittee members that think that as PTs and labs continue to mature, PTs will become more fixed limit. He is anxious to start looking at the Radiochemistry data they receive to see if it supports fixed limits.

Carl asked about a bias result when Ra-226 and Ra-228 exist in a specific ratio. Bob pointed out that this concern is with a screening test and the bias is a good thing.

Bob thanked Keith for all his effort on this topic.

5. New Standard

Bob would like the committee to start thinking about changes that might be needed in the new Standard. Ilona noted that there is a process the committee needs to follow when it is ready to start working on the next update of the Standard.

Tom noted that he doesn't have anything major, but he has several items that are logical problems or inconsistencies - incorrect emphasis on certain type of measurement. He will send an email and list them for future consideration.

Was asked whether existing issues would benefit from being addressed using SIRs. The committee will be able to review the SIRs to look for Standard issues that need to be addressed. Everyone agreed that SIRs are not used to expand the Standard. The SIRs should be reviewed as part of the Standard update.

Bob would like to start receiving input on issues that people think we should be considering in the next standard revision.

6. Prepare Standard Annotated with Summary Document Language

This is something Carolyn started, but then the committee began work on the SLH and perhaps this type of effort may not be worth the extra work. Is it duplicative?

Larry thinks the SLH has plenty of annotation and description and does not think the extra work would be any more helpful. Vas thinks it is duplication. No one thought this still needs to be done.

The effort on this will stop.

7. New Business

None.

8. Action Items

A summary of action items can be found in Attachment B.

9. Next Meeting and Close

The next meeting is scheduled for October 25, 2017 at 1pm Eastern.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

The meeting was adjourned at 2:24pm Eastern.

Attachment A
Participants
Radiochemistry Expert Committee

Members	Affiliation		Contact Information	
			Phone	Email
Bob Shannon (Chair) (2019) Present	QRS, LLC Grand Marais, MN	Other	218-387-1100	BobShannon@boreal.org
Tom Semkow (Vice Chair) (2019) Present	Wadsworth Center, NY State DOH Albany, NY	AB	518-474-6071	thomas.semkow@health.ny.gov
Sreenivas (Vas) Komanduri (2019) Present	State of NJ Department of Environmental Protection Trenton, NJ	AB	609-984-0855	Sreenivas.Komanduri@dep.state.nj.us
Marty Johnson (2019) Present	US Army Aviation and Missile Command Nuclear Counting Redstone Arsenal, AL	Lab	865-712-0275	Mjohnson@tSC-tn.com
Dave Fauth (2018) Absent	Consultant Aiken, SC	Other	803-649-5268	dj1fauth@bellsouth.net
Keith McCroan (2018) Present	US EPA ORIA NAREL, Montgomery AL	Lab	334-270-3418	mccroan.keith@epa.gov
Larry Penfold (2018) Present	Test America Laboratories, Inc; Arvada, CO	Lab	303-736-0119	larry.penfold@testamericainc.com
Ron Houck (2018*) Absent	PA DEP/Bureau of Laboratories	AB	717-346-8210	rhouck@pa.gov
Yoon Cha (2020) Present	Eurofins Eaton Analytical	Lab	213-703-5800	YoonCha@eurofinsUS.com
Candy Friday (2020) Absent	CdFriday Environmental, Inc.	Lab	713-822-1951	candy@fridayllc.com
Ilona Taunton (Program Administrator) Present	The NELAC Institute	n/a	828-712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – REC

	Action Item	Who	Target Completion	Completed
75	Prepare copy of Standard annotated with summary document language.	Carolyn	On hold	This will be moved to the Backburner page.
83	Send SLH to Ilona after final update from today so she can do editing and formatting. She will send it back to the committee for further review.	Bob/Dave Ilona	6/10/17 6/28/17	Complete
84				

Attachment C – Back Burner / Reminders

	Item	Meeting Reference	Comments
5	Form subcommittee of experts in MS and other atom counting techniques to see that these techniques are adequately addressed in the radiochemistry module.	9/24/14	

BobShannon

From: McCroan, Keith <mcCroan.keith@epa.gov>
Sent: Tuesday, September 26, 2017 2:51 PM
To: Semkow, Thomas M (HEALTH); BobShannon; candy@fridayllc.com; dj1fauth@bellsouth.net; Ilona Taunton; Keith D. McCroan; Komanduri,Sreenivas; larry.penfold@testamericainc.com; Marty Johnson; Ron Houck; Yoon Cha; Bell, Patrick; Bill_Ray@williamrayllc.com; bmiller@eraqc.com; Carl.Kircher@flhealth.gov; Carolyn Wong; Chambers, Jim; Jennifer Western; joe_pardue@charter.net; Mark McNeal; Matt Sowards; Nile Luedtke; Richard Sheibley; terry.romanko@testamericainc.com; tpatten@imlinc.com; Virgene Mulligan
Subject: RE: Outline of methods for calculating PT acceptance limits

Tom et al.,

My first inclination was to model the required variance σ^2 (or SD^2) as the sum of three components:

$$\sigma^2 = a \times AV^2 + b \times AV + c$$

The first component accounts for calibration errors, aliquot errors, yield errors, and any other errors that are proportional to the assigned value (AV). The second component accounts for the uncertainty of the counts produced by the sample. The third component accounts for the uncertainty, including counting uncertainty, of the background correction. Of course, σ then equals the square root of σ^2 .

For a real measurement process, that's generally a better model than the linear model.

Unfortunately, it seems impractical to get enough information to estimate all three parameters, a , b , and c . I considered whether we could use a two-parameter model, either

$$\sigma^2 = a \times AV^2 + c \quad \text{or} \quad \sigma^2 = a \times AV^2 + b \times AV$$

The second of these has the disadvantage that it makes σ go to zero as AV goes to zero; the first one does not. Other than that, it would be an arbitrary choice between the two, which I wasn't comfortable with. They produce very different results when you plot the curves.

When I compared these two models for σ , fitting the curves to two data points, as described in the proposal, I saw that one produced a curve that was convex (cupped upward), and one produced a curve that was concave (cupped downward). The linear model splits the difference and produces a straight line through the same two data points. The linear model also has the advantage that it has been used frequently and doesn't require us to prove to anyone that it works. TNI's current model for drinking water PT samples is linear.

I actually did not spend much time considering the third possible 2-parameter model for σ^2 :

$$\sigma^2 = b \times AV + c$$

although I could have. I knew it had the disadvantage that as AV increases toward infinity, the relative standard deviation becomes arbitrarily small. This is the only one of the models that would fully account for counting uncertainty and nothing else. For me, that's a reason not to use it.

It is important to remember that σ is a required standard deviation, not an actual standard deviation. For any real measurement process, we would *not* expect σ to follow a linear model. For a multitude of measurement processes at

many labs, we really have no idea what the curve should look like. The linear model seems as good as any and probably better than either of the other 2-parameter models that I considered.

Keith

From: Semkow, Thomas M (HEALTH) [mailto:thomas.semkow@health.ny.gov]
Sent: Tuesday, September 26, 2017 12:11
To: BobShannon <bobshannon@boreal.org>; candy@fridayllc.com; dj1fauth@bellsouth.net; Ilona Taunton <ilona.taunton@nelac-institute.org>; Keith D. McCroan <kdm@mccroan.com>; McCroan, Keith <mccroan.keith@epa.gov>; Komanduri,Sreenivas <Sreenivas.Komanduri@dep.state.nj.us>; larry.penfold@testamericainc.com; Marty Johnson <MJohnson@tsc-tn.com>; Ron Houck <rhouck@pa.gov>; Yoon Cha <YoonCha@eurofinsUS.com>; Bell, Patrick <PQBELL@southernco.com>; Bill_Ray@williamrayllc.com; bmiller@eraqc.com; Carl.Kircher@flhealth.gov; Carolyn Wong <ctwrace@gmail.com>; Chambers, Jim <Jim.Chambers@fbports.com>; Jennifer Western <jwestern@stlouisco.com>; joe_pardue@charter.net; Mark McNeal <markm@acz.com>; Matt Sowards <matts@acz.com>; Nile Luedtke <nile.luedtke@moellerinc.com>; Richard Sheibley <rhsheib111@yahoo.com>; terry.romanko@testamericainc.com; tpatten@imlinc.com; Virgene Mulligan <vmulligan@amrad.com>
Subject: RE: Outline of methods for calculating PT acceptance limits

Bob and All:

What is the meaning of SD in Equation 1? The procedure described is probably good for chemical analytes, where SD is assumed to be proportional to AV in Equation 1. In radiochemical testing, SD is usually proportional to SQRT(AV), especially when only counting uncertainty (and not total uncertainty) is allowed in SDWA for radioactivity.

Thanks – Tom Semkow

From: BobShannon [mailto:bobshannon@boreal.org]
Sent: Monday, September 18, 2017 11:47
To: Candy@FridayLLC.com; Bob Shannon <bobshannon@boreal.org>; dj1fauth@bellsouth.net; Ilona Taunton <ilona.taunton@nelac-institute.org>; Keith D. McCroan <kdm@mccroan.com>; Keith McCroan - work <mccroan.keith@epamail.epa.gov>; Komanduri,Sreenivas <Sreenivas.Komanduri@dep.state.nj.us>; larry.penfold@testamericainc.com; Marty Johnson <MJohnson@tsc-tn.com>; Ron Houck <rhouck@pa.gov>; Semkow, Thomas M (HEALTH) <thomas.semkow@health.ny.gov>; Yoon Cha <YoonCha@eurofinsUS.com>; Bell, Patrick <PQBELL@southernco.com>; Bill_Ray@williamrayllc.com; bmiller@eraqc.com; Carl.Kircher@flhealth.gov; Carolyn Wong <ctwrace@gmail.com>; Chambers, Jim <Jim.Chambers@fbports.com>; Jennifer Western <jwestern@stlouisco.com>; joe_pardue@charter.net; Mark McNeal <markm@acz.com>; Matt Sowards <matts@acz.com>; Nile Luedtke <nile.luedtke@moellerinc.com>; Richard Sheibley <rhsheib111@yahoo.com>; terry.romanko@testamericainc.com; tpatten@imlinc.com; vmulligan@amrad.com
Subject: FW: Outline of methods for calculating PT acceptance limits

ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.

All –

As I mentioned on our last call, we have been asked to contribute to the SOP the PT expert committee uses for setting PT acceptance criteria (FoPT tables). Please find the attached draft that Keith developed that could form the core of such a procedure for setting PT acceptance criteria. As it stands here, it is flexible enough to go beyond the drinking

water limits (which are the only ones currently out there). It also steps away from using study data to determine the mean which can result in sometimes significantly biased limits. We are considering several possible approaches which would possibly also allow MQO needs (explicit and implied) to be taken into account.

Please read, digest and be ready to provide opinions and constructive feedback on our call next week.

Please let me know if you have any questions or concerns.

Cheers!!

Bob

From: McCroan, Keith [<mailto:mccroan.keith@epa.gov>]
Sent: Thursday, September 14, 2017 9:16 AM
To: BobShannon; 'Komanduri, Sreenivas'
Subject: RE: Outline of methods for calculating PT acceptance limits

Bob,

If you think it's written clearly enough to be presented, I'm willing to put it out there. Or if, you think it needs more polish, I can try to polish it. I guess I hope for some positive or negative feedback on the basic approach before I spend much time on wordsmithing.

Keith

From: BobShannon [<mailto:bobshannon@boreal.org>]
Sent: Thursday, September 14, 2017 08:58
To: McCroan, Keith <mccroan.keith@epa.gov>; 'Komanduri, Sreenivas' <Sreenivas.Komanduri@dep.nj.gov>
Subject: RE: Outline of methods for calculating PT acceptance limits

Vas and Keith –

What do you think? I would like to put something out there for folks to read and digest before our meeting.

Bob

From: McCroan, Keith [<mailto:mccroan.keith@epa.gov>]
Sent: Monday, September 11, 2017 1:12 PM
To: BobShannon; 'Komanduri, Sreenivas'
Subject: RE: Outline of methods for calculating PT acceptance limits

Here is revision 2.

I've generalized it further and included an option to evaluate the lab on the basis of its own stated performance capabilities.

I haven't tried to describe what might be necessary to evaluate labs based on their reported measurement uncertainties. The over-simplified version would say just replace SD by the CSU, but as you know, I think that would raise a lot of questions that we would then be expected to answer.

Keith

From: McCroan, Keith

Sent: Tuesday, September 05, 2017 13:47

To: 'BobShannon' <bobshannon@boreal.org>; 'Komanduri, Sreenivas' <Sreenivas.Komanduri@dep.nj.gov>

Subject: RE: Outline of methods for calculating PT acceptance limits

Here is a revised proposal, with a new equation for c designed to produce a specified relative standard deviation at a specified high activity. With that comes a recommendation to make sure that c can't be less than some predetermined minimum value (e.g., 2 or 3 %).

I'm also attaching a revised Excel workbook that implements it. You can change the values of k and min c to anything you want. You can also replace the definition of r. I've got it defined as QC/k, but you can change it to RMSE. Just remember to refresh the pivot table to be sure the changes are reflected on the graph.

From: McCroan, Keith

Sent: Tuesday, September 05, 2017 08:25

To: 'BobShannon' <bobshannon@boreal.org>; 'Komanduri, Sreenivas' <Sreenivas.Komanduri@dep.nj.gov>

Subject: RE: Outline of methods for calculating PT acceptance limits

I played with Excel over the long weekend, comparing the old limits with different options for new limits. I'm attaching the workbook so that you can try all the options and see for yourself. The QC limits are currently those for LFBs, except for gross alpha, which I think should be a special case.

I've been dividing the recommended QC limits (either LFB or MS) by 2 to get the required standard deviation. The cert manual says the control limits are 3-sigma limits (which is inconsistent with the manual's RER criteria for duplicate precision BTW). The recommended limits are just bounds for what the 3-sigma control limits "should" be. Apparently, the 3-sigma limits can be biased, but the recommended bounds for those limits are given relative to the true value (i.e., without bias). So, I think we could divide the bounds by either 2 or 3 to get a required standard deviation. My workbook currently divides them by k=2.

In many cases, our new limits at the DL would be a lot larger than the old. The old limits usually require much better than a 51 % relative standard uncertainty at the DL.

I feel a little reluctant to expand the acceptance ranges for gamma-emitters or tritium a lot at the high end of the testing range. I'm also reluctant to shrink the ranges for gross alpha, gross beta, Ra-226, or Ra-228 very much.

I'll let you look and form your own conclusions.

From: BobShannon [<mailto:bobshannon@boreal.org>]

Sent: Wednesday, August 30, 2017 15:27

To: McCroan, Keith <mccroan.keith@epa.gov>; 'Komanduri, Sreenivas' <Sreenivas.Komanduri@dep.nj.gov>

Subject: RE: Outline of methods for calculating PT acceptance limits

FYI –

I talked to Glynda Smith in broad strokes about our updating the PT acceptance limits.

She was in support of eliminating the biased limits. Otherwise, it was my impression that she would likely go with the flow of what we recommend to her – assuming it is not too radically different. Once we finalize the approach we think we might use, we can bounce this off of her again.

Bob

From: BobShannon [<mailto:BobShannon@boreal.org>]
Sent: Wednesday, August 30, 2017 2:27 PM
To: 'McCroan, Keith'; 'Komanduri, Sreenivas'
Subject: RE: Outline of methods for calculating PT acceptance limits

I agree with what you write, Keith.

From my experience, it may be difficult to expect much better performance from gross alpha than the “10%” target Keith mentions, especially when sample solids are present. There are several good technical reasons that limit the performance, not the least of which would be the impact of variable solids composition on results. For what it is worth, here is a summary of ERA Gross Alpha results

Summary of Method Performance Data for ERA Gross Alpha PT Studies 55-99 Results

Method	Data Points	Average	Std. Dev.	Min.	2.5 percentile	Median	97.5 percentile	Max	
Gross Alpha	EPA 900.0	1537	95%	24%	27%	52%	93%	148%	246%
	EPA 00-02	223	91%	20%	40%	49%	93%	130%	195%
	SM 7110 C	198	92%	16%	7.5%	62%	92%	124%	133%
	SM 7110 B	161	97%	22%	7.2%	54%	98%	137%	174%
All Methods	2119	94%	23%	7.2%	52%	93%	143%	246%	

I hope that the new method 900.0 will improve lab intercomparability since it will allow them to begin using a common solids mixture for calibration. It will also be important at that point to talk to ERA about using a matrix that matches the methods solids mixture.

Let's plan on talking in September so we have some time to work on this before our next meeting.

Bob

From: McCroan, Keith [<mailto:mccroan.keith@epa.gov>]
Sent: Wednesday, August 30, 2017 1:52 PM
To: Komanduri, Sreenivas
Cc: Bob Shannon
Subject: RE: Outline of methods for calculating PT acceptance limits

1. It wouldn't be a fixed percentage. Bob's hope is that we can have a testing range that starts at zero, and the standard deviation at zero would not be zero. The standard deviation would instead be calculated as a linear function of AV, and it would have a positive value at AV = 0. The *relative* standard deviation would be largest at low concentrations and would decrease as the concentration increased, gradually approaching a limit.
2. When I say “three components,” I mean three components of the variance, or three terms added together to get the total variance---not three concentration levels.
3. I'm not sure that we have to assume reagent water instead of a simulated drinking water. But if that's the case, we could consider LFB limits instead of MS. If it cuts the acceptance range down considerably from what it has been in the past, we'll also need a strong rationale for that.

From: Komanduri, Sreenivas [<mailto:Sreenivas.Komanduri@dep.nj.gov>]
Sent: Wednesday, August 30, 2017 13:09
To: McCroan, Keith <mccroan.keith@epa.gov>
Cc: Bob Shannon <bobshannon@boreal.org>
Subject: RE: Outline of methods for calculating PT acceptance limits

Good afternoon Keith,

Thank you for the response. To continue with the discussion, some more for consideration.

1. You and I thought that a 20% range (LL and UL) sounds reasonable. See below. The question is whether the 20% is reasonable for the entire concentration range of 7 to 75pCi/L for gross alpha? It will be easy to justify at the lower end of the scale. At higher end, a 20% may not provide enough challenge to the capability of the participant labs.
2. You have indicated a three component system. I guess you were referring to the concentration range as being composed of three levels. If so, a segmented approach for the levels be appropriate? Will that be too cumbersome to implement? It would be interesting to know how ERA (the only provider) existing system is set up. If we know for sure that there is a segmented approach (not necessarily for RAD or Gross Alpha), then it will be easy to push the idea.
3. Also, when a PT is prepared, it is prepared using reagent water (similar to LFB). How can we justify 20% instead of 10% if when we say it is based that on the DW Manual? It will be tricky. We need a better rationale.

I expect Bob to weigh-in and a future call to discuss. Thank you again.

Vas

From: McCroan, Keith [<mailto:mccroan.keith@epa.gov>]
Sent: Monday, August 28, 2017 4:47 PM
To: Komanduri, Sreenivas <Sreenivas.Komanduri@dep.nj.gov>
Cc: Bob Shannon <bobshannon@boreal.org>
Subject: RE: Outline of methods for calculating PT acceptance limits

Thanks, Vas.

3. I think I'd prefer the MS limits over the LFB limits. I interpret $\pm 10\%$ as a 5% required standard deviation and $\pm 20\%$ as a required 10% standard deviation. For gross alpha and beta, the limits are larger, I think, and they should be.

If that sounds reasonable, I can produce a plot for each of the analytes in the old table. Each plot would show the old limits and the new limits on one graph.

4. It might make it easier to pass PTs for analytes whose acceptance limits have been asymmetric in the past. For example, if 60% recovery was acceptable in the past but 140% was not, we might make both 60% and 140% recoveries equally acceptable in the future. On the other hand, it appears that some of the lowest recoveries that were acceptable before would become unacceptable.

I think you're asking the right questions.

Keith

From: Komanduri, Sreenivas [<mailto:Sreenivas.Komanduri@dep.nj.gov>]
Sent: Monday, August 28, 2017 15:22
To: McCroan, Keith <mccroan.keith@epa.gov>
Cc: Bob Shannon <bobshannon@boreal.org>
Subject: RE: Outline of methods for calculating PT acceptance limits

My initial comments are follows.

1. It is a whole new approach for RAD PTs. The criteria is based on the assigned value (AV) which is better than the participant mean (PM) of the existing procedure.
2. RMSE also new for acceptance limits around the AV.
3. The calculation of c and d , can be tricky. If option 2 looks better as you suggested. The difficulty comes which one to pick. LFB or MS? The limits are not the same for both. LFB, $\pm 10\%$ and MS $\pm 20\%$ (allowed) of the target value as per the Manual. It would be interesting to see how the table looks with such limits.
4. If this new approach avoids bias on the part of the participant (I don't know, how that is true), how that effects the PT? Will it make more likely to pass PT every time?

Overall, the approach is new in many respects, relatively straight forward (compared to the existing) and certainly deserve further discussion.

Thanks, appreciate it.

Vas

From: McCroan, Keith [<mailto:mccroan.keith@epa.gov>]

Sent: Wednesday, August 23, 2017 10:14 AM

To: Bob Shannon <bobshannon@boreal.org>; Komanduri, Sreenivas <Sreenivas.Komanduri@dep.nj.gov>

Subject: RE: Outline of methods for calculating PT acceptance limits

The attached workbook shows the effect of implementing symmetric acceptance limits for gross alpha based on root mean squared error. I'm just taking the current values for μ and σ and calculating the limits in two different ways. If we really implemented the model, we would have new values for μ and σ .

The mean μ and standard deviation σ are calculated using the existing parameters a , b , c , and d . The old (biased) acceptance limits are shown as LL1 and UL1.

The root mean squared error is then calculated from μ and σ . The new (unbiased) acceptance limits are shown as LL2 and UL2.

Outline of Proposed Methods for Calculating PT Acceptance Criteria

For any PT matrix and analyte, the center of the acceptance range is the assigned value (AV), determined when the PT samples are prepared. The acceptable standard deviation, SD , is a function of AV , calculated as

$$SD = c \times AV + d \quad (1)$$

where c and d are parameters specific to the matrix and analyte. The lower and upper acceptance limits are

$$LL = AV - 2 \times SD \quad \text{and} \quad UL = AV + 2 \times SD \quad (2)$$

Set the lower end of the testing range at 0. How do we determine the upper end of the testing range? At least 5 times the MCL, if applicable. What else?

There are at least four options for determining the parameters c and d . The options are:

1. Determine the parameters from the program's measurement quality objectives (MQOs), if applicable. For example, the values of c and d may be based on bias and precision requirements for measurements of low-activity and high-activity samples.
2. Determine the parameters from the program's quality control (QC) requirements. For example, the value of c may be based on acceptance limits for matrix spikes or laboratory control samples.
3. Determine the parameters from the participant's stated performance capabilities (e.g., detection limit and quantification limit).
4. Determine the parameters from the mean squared error observed in historical participant data.

Combinations of these options may also be possible.

Given two specified activity concentrations, denoted by L (for "low") and H (for "high"), and the required standard deviations at each (σ_L at L and σ_H at H), calculate the parameters c and d as follows:

$$c = \frac{\sigma_H - \sigma_L}{H - L} \quad \text{and} \quad d = \sigma_L - L \times c \quad (3)$$

Round the calculated values of both c and d to 4 figures. Require that c and d be positive. Choose a minimum possible value for c , which must be positive, and replace c by that minimum value if the calculated value is smaller.

The required standard deviations, σ_L and σ_H , may be determined from required relative standard deviations (RSDs) at L and H .

$$\sigma_H = H \times RSD_H \quad \text{and} \quad \sigma_L = L \times RSD_L \quad (4)$$

For drinking water PT samples, take the lower concentration L to be the required detection limit (DL), where the required relative standard deviation is always $RSD_L = 1 / 1.96$. It should suffice to take the higher concentration H to be the upper end of the PT testing range, with the required relative standard deviation at H based on the QC requirements in the EPA's drinking water certification manual. Divide the relative QC tolerance by either 2 or 3 to obtain RSD_H . Then use equations 3 and 4 to calculate c and d .

For other programs having stated precision requirements, apply similar logic. For example, if there is a required MDC, let L be the MDC and let $RSD_L = 0.3$. If there is a required MQC (minimum quantifiable concentration), let H be the MQC and let $RSD_H = 0.1$.

The same logic works when the lab is evaluated on the basis of its own stated performance capabilities at two activity concentrations, L and H . The lab's capabilities might be stated either in terms of the required relative standard deviations at L and H or in terms of the required MDC and MQC.

If there are no relevant requirements or objectives for precision, use historical PT data to determine both c and d , fitting a curve to all the data, excluding outliers, obtaining c and d as the curve parameters to calculate the root mean squared error ($RMSE$) as a function of AV . Equate $RMSE$ with SD .

Note that since the acceptance limits are symmetric about AV , the criteria provide no incentive for participants to avoid correcting biases in their measurement processes.