Quality Control and Assurance

LECTURE 4

Learning objectives: Precision, Quality Control, Quality Assessment and Cross Calibration

Phobias and Irrational fears

DXA Quality Control Processes

Instrument QC

Pre-Scan calibration

Weekly phantom scanning

Monthly phantom scanning

Service log entries

Scanner preventative maintenance by manufacturer

Precision testing by the technologist

You must scan patients on a scanner with a database that represents their demographics. Therefore, it is imperative that you do the DXA scans preferably at the same clinic, same scanner, using the same technologist every time.

Optimum Situations

- Limit number of scanning personnel
- Daily calibration and/or QC of system
- Weekly QC (not all systems will use this)
- Precision study
  - Have you done one yet?

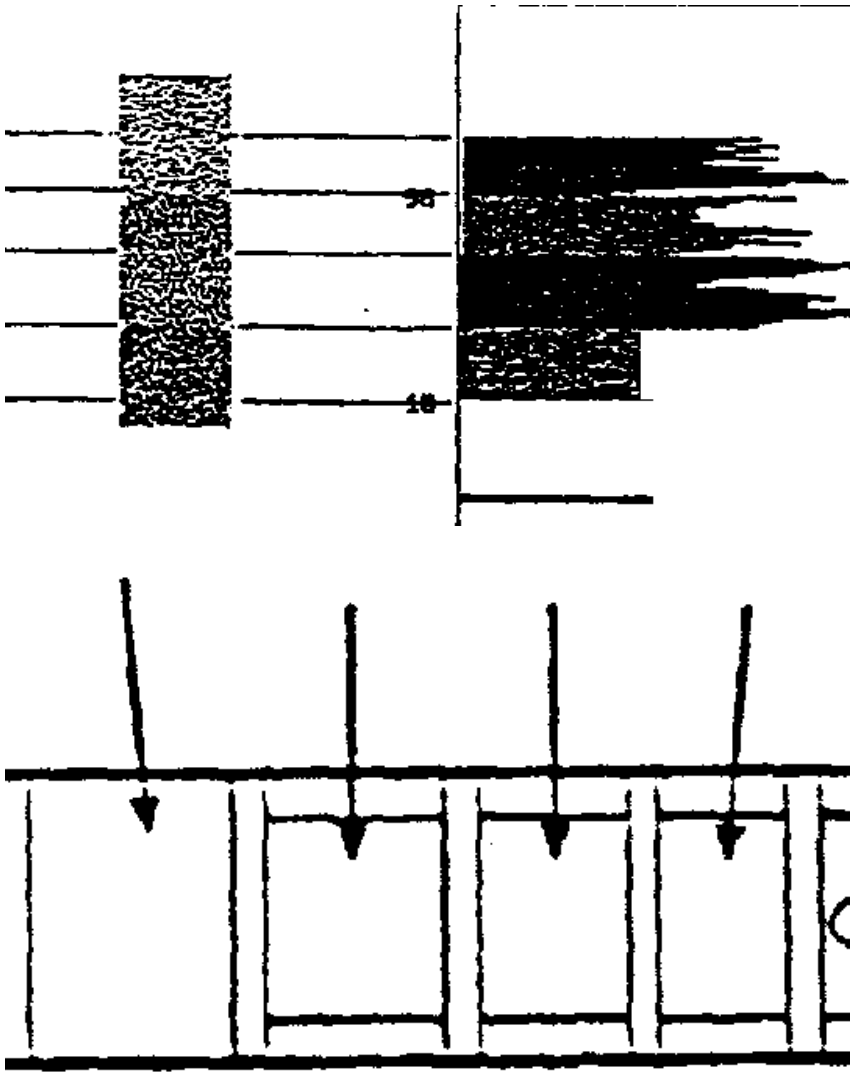
Limiting Personnel

“looks good on paper”	Try to match tech to machine to patient	Try to be consistent in scanning protocols by setting down rules for facility
• Not always practical in today’s world		• You should have written work instruction

Daily Calibrations

All DXA scanners utilize some kind of consistent calibration tool.

- Calibration box
- Anthropomorphic spine phantom
- Step-wedge phantom



Phantoms/Standards

Step-wedge

Phantoms/Standards

Anthropomorphic phantom

Resembles anatomy which is being evaluated

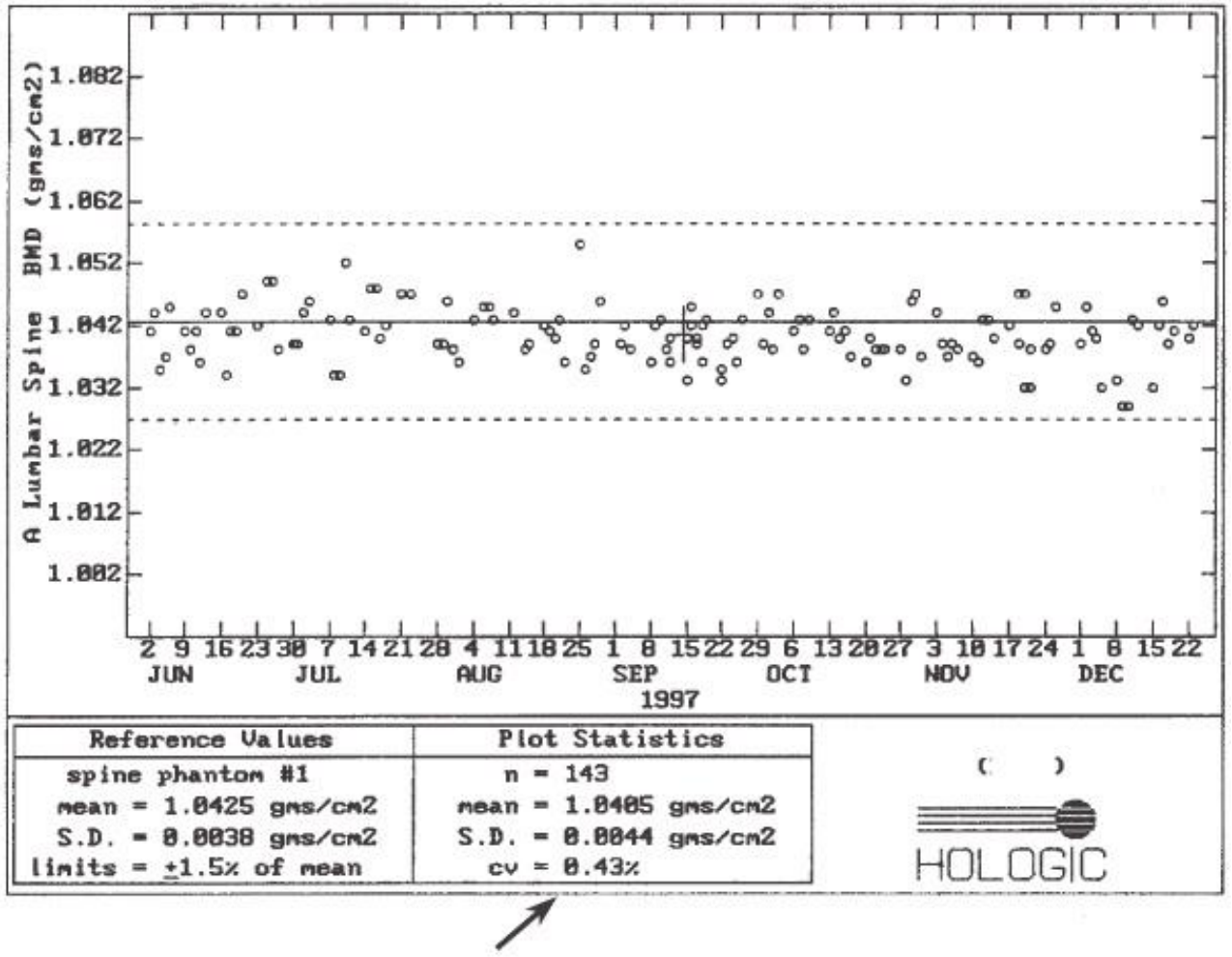
Results from Phantom Scan

Area measurement

- Bone Mineral Content (BMC)
- Bone Mineral Density (BMD)

BMD is plotted on QA graph

This BMD should fall +/- 1.5 % of established BMD of system



Results from Phantom Scan

Results from Phantom Scan

What do you do with this information?

- Print the QC scan
- Check this printout
- Initial or sign off on it
- Place in QC book for facility
- These steps document you are visualizing your QC Scan and not just running them to get going on your day.

Daily Calibration Process

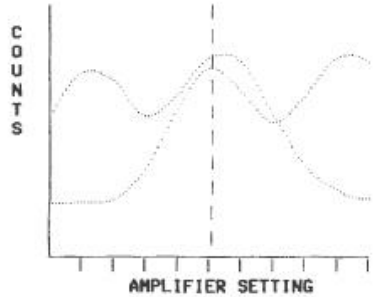
"Wakes up the machine"

Verifies and evaluates:

- Internal machine mechanics
- Electronics of scan table
- Function of laser light
- Detector system for the dual beam
- CV for the scan

QUALITY ASSURANCE RESULTS

X-Ray Voltage (kVp)	76.0	Date	02/26/98
X-Ray Current (μA)	150.0	System	1



DETECTOR

AMPLIFIER SETTING	COUNTS LOW keV	COUNTS HIGH keV
220	41718	566
270	62826	934
320	59491	2483
370	42653	16576
420	52944	45827
470	70502	65478
520	68755	54464
570	43482	39603
620	18819	52320
670	6986	70416
720	2714	68669

PROCEDURE	VALUE	EVALUATION
Lights	-	Pass
Peak Setting	475 units	Pass
Background (Low keV)	0 cps	
(High keV)	1 cps	Pass
Beam Stop Action	-	Pass
Percent Spillover	7.56 %	Pass - Good
Chi Square	5	Pass
Air Counts (Low keV)	762830 cps	Pass
(High keV)	445833 cps	Pass
Air Ratio	0.58	Pass
Transverse Mechanics	12386/12389 steps	Pass
Longitudinal Mechanics	19720/19721 steps	Pass
Tissue Value	1.309	Pass
Collimation Ratio	3.865	Pass

	1	2	3	4	5	MEAN	SD	%CV
LARGE BM	267.8	267.2	265.9	266.5	267.6	267.0	0.69	0.26
WIDTH	498	502	501	502	499	500	1.62	0.32
MEDIUM BM	200.4	198.6	197.8	197.2	196.3	198.0	1.41	0.71
WIDTH	429	433	432	432	428	431	1.94	0.45
SMALL BM	143.6	142.4	141.4	140.3	142.5	142.1	1.12	0.79
WIDTH	365	364	364	363	363	364	0.75	0.21

Courtesy GE-Lunar, Madison, Wis.

Daily Calibration-GE Lunar

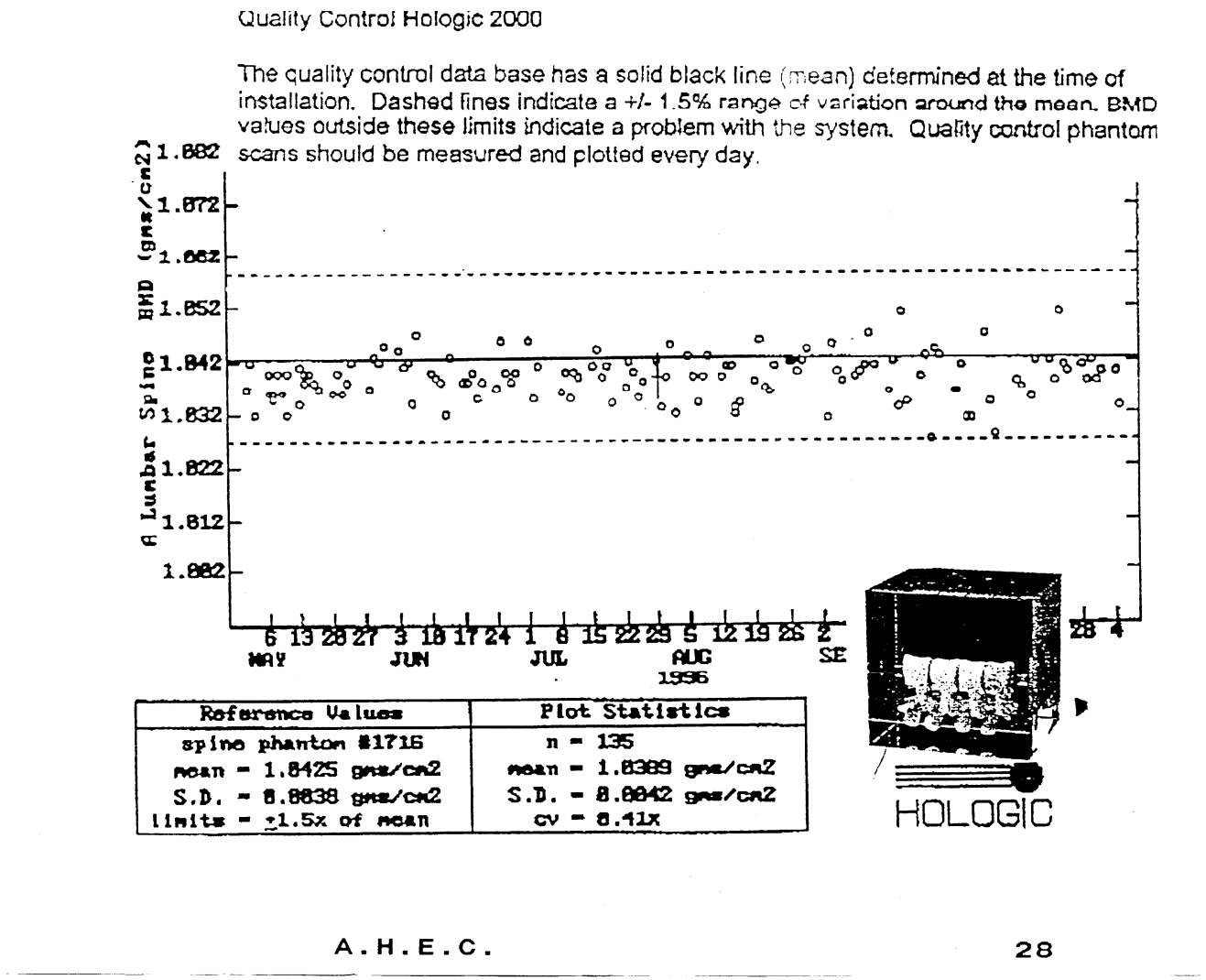
Where does the baseline come from?

Machine is brought to facility

Taken out of boxes and assembled

Baseline scans are performed

- Typically, 10 phantom scans without repositioning phantom
- Scans are averaged to produce a mean
- Range of performance or CV is calculated from mean
- Data is entered by engineer into system



Scan QC Information Baseline

What can change from day to day?

Operators

The patient

Machine performance or fluctuation

- Changes in phantom measurements

Measuring Precision

BMD can vary due to:

Site measured

- PA Lumbar
- Hip
- Forearm

Measuring Precision

Type of densitometer

- Manufacturer
- Model of machine
- Age of Software

Operator

- Experienced vs. Inexperienced

Method of measurement

- RA, DXA, QCT, QUS

Precision Study

What is accuracy?

- When does it occur?
- How is it affected?

What is precision?

- When does it occur?
- How do we measure it?

Accuracy

Does the BMD measurement produced by your machine reflect the true value of your patient's BMD

Or-"Do you have what we say you have?

Would it match results from a core biopsy of your patient?

Provides amount of BMD for region

Allows us to assign

T-Score

Z-Score

Accuracy

Accuracy

Occurs first time you measure a patient's BMD

We assign a classification of BMD

Is affected by:

Type of device	Positioning of patient	Patient prep	Skill of technologist	Analysis process

Accuracy

Do you ever drop the ball in some of these critical areas?

Sure, we do

What can you do differently?

- Get some training
- Make changes as you grow in your skills

Precision

Reproducibility of results?

Can you duplicate the measurement the next time the patient comes back?

What can you do to help achieve this goal?

Look at previous scans	Compare them for performing your analysis	Duplicate, duplicate, duplicate

Types of Precision Studies

In Vitro

- Related to design of instrument
- Appropriate and timely maintenance of system
- Evaluated using a phantom

In Vivo

- Based upon operator skills
- This can be more difficult to measure
- Uses live subjects, not a phantom

Precision Occurs

- When patient returns for serial measurements
- Involves an in-house precision study
- Perform one in your facility prior to doing follow-up measurements

Precision Study

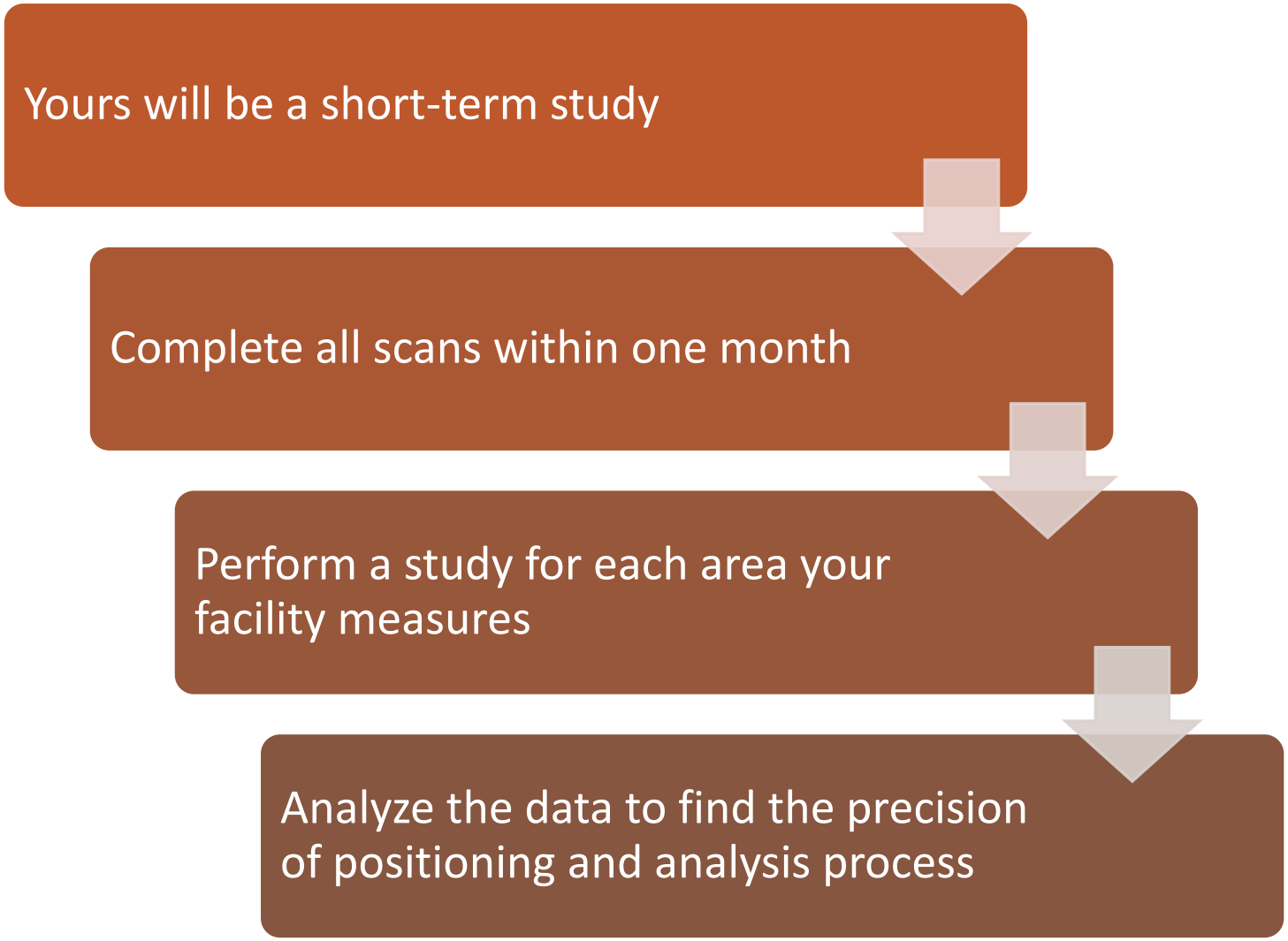
***Make sure it is legal in your state to perform study with live subjects

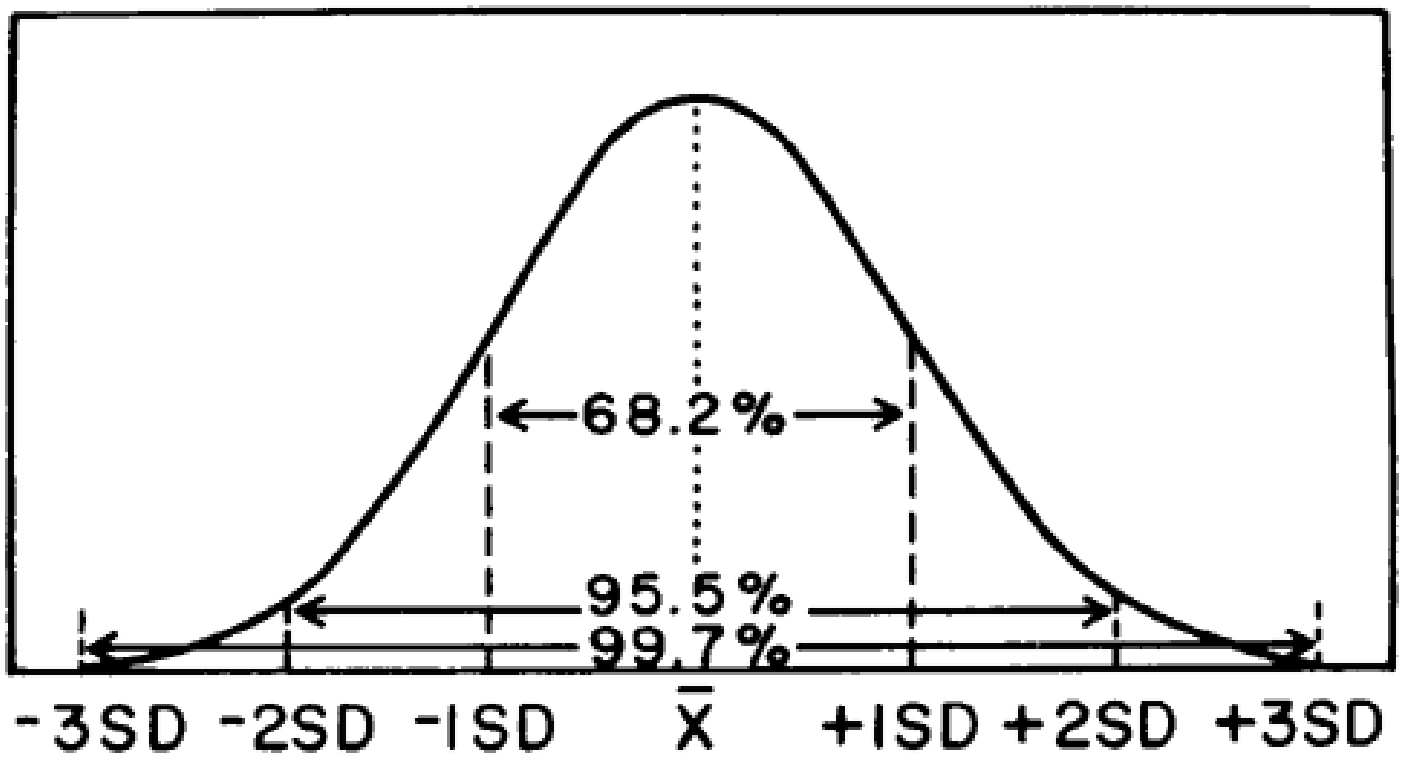
Document the patient has consented to be involved in study

Develop a document for your facility which the patient will sign verifying they understand the following:

- They will be participating in a study
- They will receive some additional exposure with additional scan

Precision Study





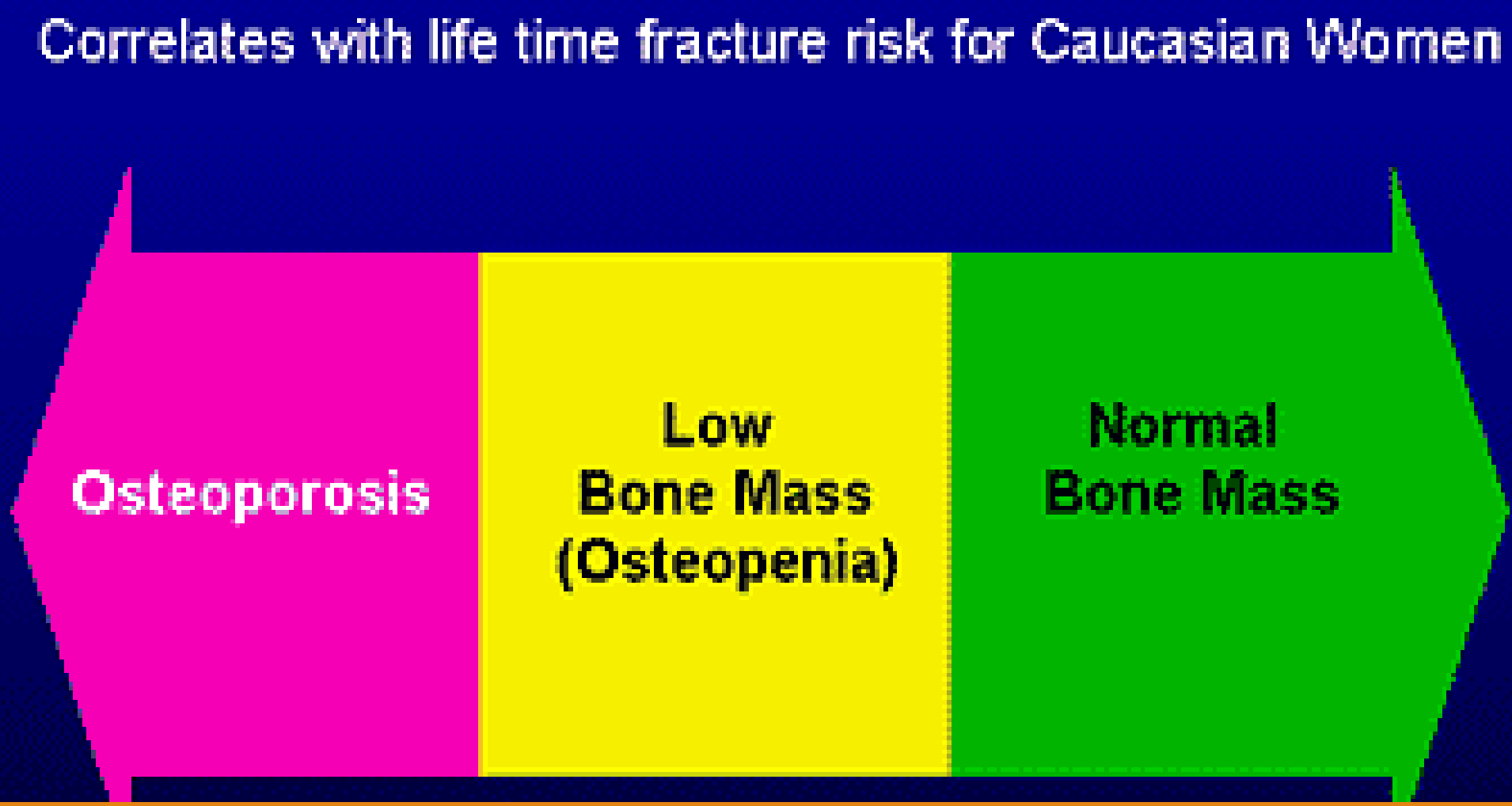
Terminology

Mean

- Average value of a group of measurements

Standard Deviation (SD)

- Standard variation or deviation from mean value



How is the SD used in BMD?

CV

Coefficient of Variation (CV)

- SD as expressed as a percentage of the mean
- CV= 100 X (SD/Mean)

Smaller CV, the better the precision of the result or value

I.E.- a CV of 2% is better than 5%

Why should we measure precision?

Doesn’t the manufacturer do it?

Can’t I use their data?

Manufacturers uses:

- Phantoms or healthy individuals
- Highly skilled technologists

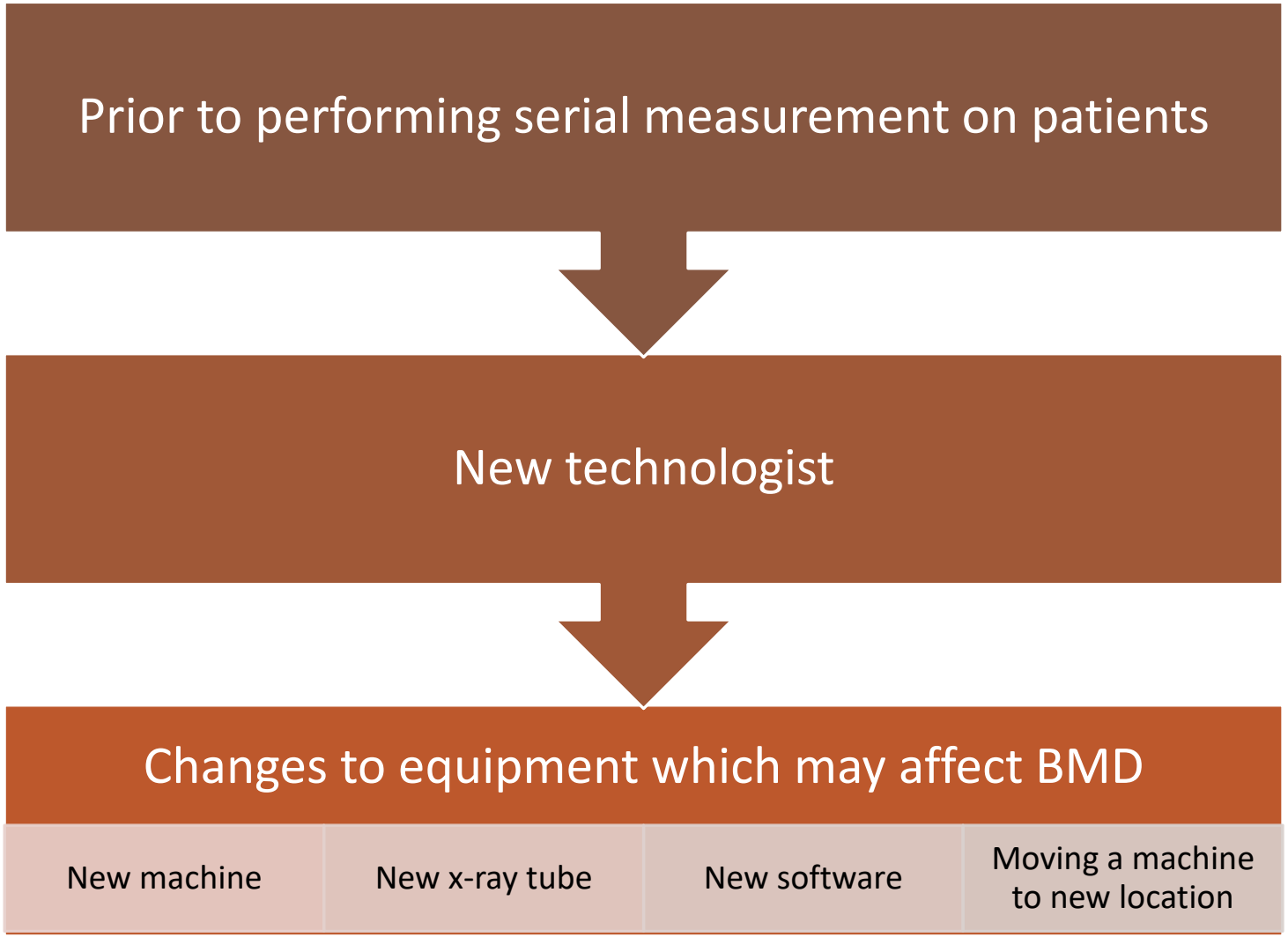
What's happening in my facility?

Older patients

- Degenerative changes
- Medication changes
- Loss of a site to measure

Newer operators

- Learning the ropes
- Do not know all the ins and outs of machine



When do we measure precision?

How do we do it?

Within one month

Same technologist

Same site

- 30 patients -2 times
- 15 patients -3 times

The individual values and the average value for each of the 3 scans on patients 1 thourgh 14 are shown in table 1.

PATIENT	SCAN 1	SCAN 2	SCAN 3	MEAN (X)
Patient 1	1.010	1.019	1.100	1.043
Patient 2	0.925	0.940	0.918	0.928
Patient 3	1.164	1.160	1.170	1.165
Patient 4	0.999	1.010	1.008	1.006
Patient 5	0.900	0.920	0.905	0.908
Patient 6	0.955	0.960	0.960	0.958
Patient 7	1.000	1.010	1.150	1.053
Patient 8	0.875	0.849	0.869	0.864
Patient 9	0.898	0.920	0.901	0.906
Patient 10	1.111	1.009	1.100	1.073
Patient 11	0.964	0.949	0.960	0.958
Patient 12	1.000	0.985	0.992	0.992
Patient 13	1.200	1.185	1.205	1.197
Patient 14	1.165	1.170	1.180	1.172

Table 1. The Individual and Mean Values for AP Spine Studies on 14 Patients

A Question

WHAT IF WE HAVE MORE THAN ONE TECH?

Precision Study

Use precision calculation formula

Use ISCD precision calculation software

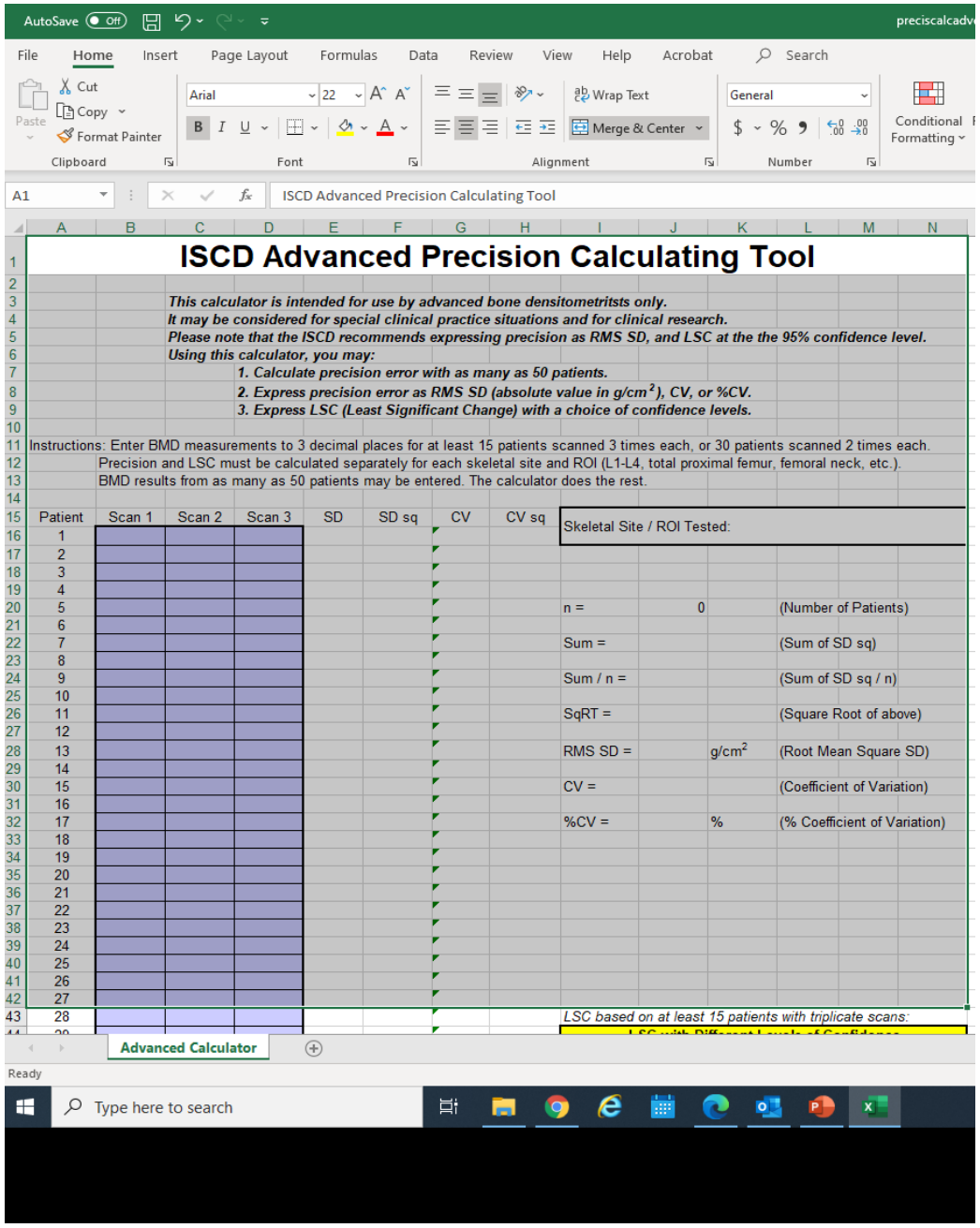
Study will provide basis to determine amount of change in BMD on serial exams to be declared significant

Precision Study for DEXA L-Spine (Endocrine Clinic of Southeast Texas) 9/2/98

BMD (gm/cm2)	-(Mean)	Difference	Difference Squared
1.094	-1.11725	-0.02325	0.000540563
1.081	-1.11725	-0.03625	0.001314063
1.086	-1.11725	-0.03125	0.000976563
1.082	-1.11725	-0.03525	0.001242563
1.119	-1.11725	0.00175	0.000003063
1.104	-1.11725	-0.01325	0.000175563
1.101	-1.11725	-0.01625	0.000264063
1.126	-1.11725	0.00875	0.000076563
1.121	-1.11725	0.00375	0.000014063
1.145	-1.11725	0.02775	0.000770063
1.133	-1.11725	0.01575	0.000248063
1.160	-1.11725	0.04275	0.001827563
1.112	-1.11725	-0.00525	0.000027563
1.121	-1.11725	0.00375	0.000014063
1.116	-1.11725	-0.00125	0.000001563
1.106	-1.11725	-0.01125	0.000126563
1.138	-1.11725	0.02075	0.000430563
1.124	-1.11725	0.00675	0.000045563
1.138	-1.11725	0.02075	0.000430563
1.140	-1.11725	0.02275	0.000517563
1.138	-1.11725	0.02075	0.000430563
1.117	-1.11725	-0.00025	0.000000063
1.105	-1.11725	-0.01225	0.000150063
1.116	-1.11725	-0.00125	0.000001563
1.125	-1.11725	0.00775	0.000060063
1.107	-1.11725	-0.01025	0.000105063
1.110	-1.11725	-0.00725	0.000052563
1.118	-1.11725	0.00075	0.000000563
31.283			
		Sum of squared differences	0.009847264
		Divided by 27	0.000364713

Standard deviation: 0.019097473 gm/cm2

Coefficient of variation: 0.017093285 or 1.7%



ISCD Advanced Precision Calculating Tool

This calculator is intended for use by advanced bone densitometritsts only.
It may be considered for special clinical practice situations and for clinical research.
Please note that the ISCD recommends expressing precision as RMS SD, and LSC at the the 95% confidence level.
Using this calculator, you may:

1. ***Calculate precision error with as many as 50 patients.***
2. ***Express precision error as RMS SD (absolute value in g/cm^2), CV, or %CV.***
3. ***Express LSC (Least Significant Change) with a choice of confidence levels.***

Instructions: Enter BMD measurements to 3 decimal places for at least 15 patients scanned 3 times each, or 30 patients scanned 2 times each.
Precision and LSC must be calculated separately for each skeletal site and ROI (L1-L4, total proximal femur, femoral neck, etc.).
BMD results from as many as 50 patients may be entered. The calculator does the rest.

Patient	Scan 1	Scan 2	Scan 3	SD	SD sq	CV	CV sq
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
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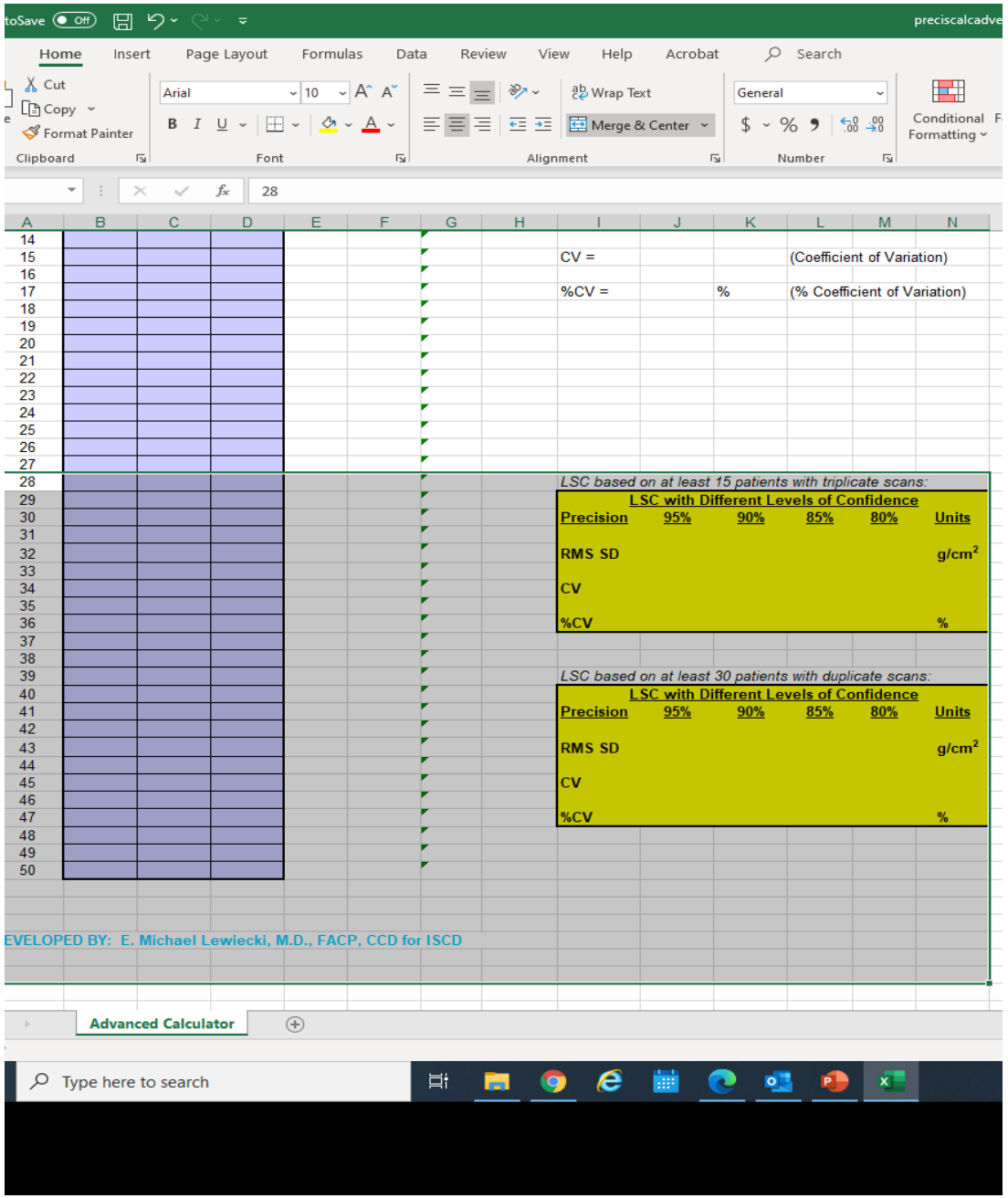
22							
23							
24							
25							
26							
27							
28							

Skeletal Site / ROI Tested:

n =	0	(Number of Patients)
Sum =		(Sum of SD sq)
Sum / n =		(Sum of SD sq / n)
SqRT =		(Square Root of above)
RMS SD =	g/cm^2	(Root Mean Square SD)
CV =		(Coefficient of Variation)
%CV =	%	(% Coefficient of Variation)

LSC based on at least 15 patients with triplicate scans:



CV = (Coefficient of Variation)

%CV = % (% Coefficient of Variation)

LSC based on at least 15 patients with triplicate scans:

LSC with Different Levels of Confidence

Precision	95%	90%	85%	80%	Units
RMS SD					g/cm^2
CV					
%CV					%

LSC based on at least 30 patients with duplicate scans:

LSC with Different Levels of Confidence

Precision	95%	90%	85%	80%	Units
RMS SD					g/cm^2
CV					
%CV					%

EVELOPED BY: E. Michael Lewiecki, M.D., FACP, CCD for ISCD

How do you use the data?

Take the precision error for the site measured and subtract it from the amount of BMD change from the previous scan

This is your clinically significant BMD change.

For example

If your BMD error for the system and your scanning personnel is:

5% error for the L-Spine

10% error for the Total Hip

For example

Your patient's BMD in the L-Spine has changed 6.5% and 15% in the Total hip since the previous BMD measurement

How much of this BMD change is clinically significant?

DXA Cross Calibration

Machine Cross Calibration

Should be performed when adding a new DXA machine to your facility.

When replacing an old DXA scanner of the same manufacture.

When getting a software upgrade.

When replacing an x-ray tube (Use the precision study from the x-ray tube that went out).

ISCD Machine Cross Calibration Tool