SHINE™ Medical Technologies

September 2, 2015

SMT-2015-040
10 CFR 50.30

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References:
(1) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)
(2) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)
(3) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 26, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report (ML15239B051)
(4) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 27, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report

SHINE Medical Technologies, Inc. Application for Construction Permit
Response to Request for Additional Information

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, Inc. (SHINE) submitted an application for a construction permit to construct a medical isotope facility to be located in Janesville, WI (References 1 and 2). Via References (3) and (4), the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE construction permit application.

Enclosure 1 provides the SHINE response to the NRC staff's request for additional information.

If you have any questions, please contact Mr. Jim Costedio, Licensing Manager, at 608/210-1730.

A001
NRR

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on September 2, 2015.

Very truly yours,

for VANN BYNUM

R. Vann Bynum, Ph.D.
Chief Operating Officer
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosure

cc: Administrator, Region III, USNRC
Project Manager, USNRC
Environmental Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

The NRC staff determined that additional information was required (References 1 and 2) to enable the continued review of the SHINE Medical Technologies, Inc. (SHINE) application for a construction permit to construct a medical isotope facility (References 3 and 4). The following information is provided by SHINE in response to the NRC staff's request.

CHAPTER 6 – ENGINEERED SAFETY FEATURES

Section 6b.3 – Nuclear Criticality Control

(Applies to RAIs 6b.3-31 through 33)

> *As required by 10 CFR 50.34(a), "Contents of applications; technical information," a preliminary safety analysis report should include "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility..., and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents." Additionally, the preliminary design of the facility should provide reasonable assurance to the NRC staff that the final design will conform to its design bases with adequate margin for safety.*
>
> *With respect to nuclear criticality control, the Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part that "[c]riticality process safety controls should be provided for criticality safety, and a description of their safety function should be described. The applicant should use enough safety controls to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical" and that "NCS [nuclear criticality safety] limits on controlled parameters will be established to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety."*

RAI 6b.3-31

The ISG augmenting NUREG-1537, part 2, Section 6b.3, contains criteria for the use of mass, geometry, density, enrichment, reflection, moderation, concentration, interaction, neutron absorbers, and volume as controlled parameters. Additional information is needed in order for NRC staff to determine the adequacy of SHINE's treatment of controlled parameters in order to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety. Specifically, SHINE's construction permit application does not contain the necessary commitments to following technical practices for the use of each controlled parameter in order demonstrate a sufficient design basis in its preliminary design.

In order to provide reasonable assurance that SHINE's final design will conform to its design bases with adequate margin for safety, as required by 10 CFR 50.34, commit to following technical practices for the use of each controlled parameter described in the ISG augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," or state that reliance on particular parameters will not be used. For those parameters that are not controlled, commit to assuming the most reactive credible conditions. Additionally, describe any conservatism in the calculated keff resulting from the use of these technical practices.

SHINE Response

SHINE will follow the technical practices for the use of each controlled parameter (i.e., mass, geometry, density, enrichment, reflection, moderation, concentration, interaction, neutron absorbers, and volume) described in Section 6b.3 of the Interim Staff Guidance (ISG) augmenting NUREG-1537, Part 2 (Reference 5). These practices are listed on Pages 72 through 74 of the ISG augmenting NUREG-1537, Part 2. For those parameters that are not controlled, SHINE will assume the most reactive credible conditions.

The conservatisms in the calculated k_{eff} values from the use of these technical practices for Atkins-NS-DAC-SHN-15-02, Revision 0, provided as Attachment 3 to Enclosure 1 of Reference (6), and Atkins-NS-DAC-SHN-15-04, Revision 0, provided as Attachment 2 to Enclosure 1 of Reference (6), are described below. These conservatisms result in a higher calculated k_{eff} value.

Atkins-NS-DAC-SHN-15-02, Revision 0

- Mass, Concentration: Solute saturation is assumed to be unlimited. Realistic saturation behavior is ignored in favor of showing the peak reactivity for the various materials regardless of concentration.
- Geometry: The vessel walls are assumed to be made of the fissile material being analyzed, effectively removing the need for measurements of vessel thickness with respect to nuclear criticality safety (NCS).
- Enrichment: Uranium is assumed to be enriched to 21 wt% ^{235}U, an increase over the nominal value of 19.75%.
- Reflection: Concrete reflector walls are located six inches from the outside of the neutron absorber panel. This is a conservative estimate of the minimum anticipated distance.
- Reflection: Void and water flooded conditions are modeled in order to determine the most reactive conditions.
- Moderation: Uranyl sulfate is modeled assuming no excess acid as a conservative simplification. Excess acid would reduce moderation and increase neutron absorption.
- Neutron absorbers: The manufacturer specification for the minimum hydrogen density in the PPC-B is used. Minimum hydrogen density will result in the least amount of scattering in the absorber and thus the least amount of neutron absorption.
- Neutron absorbers: Only 75% of the calculated boron density is used for the PPC-B. This is a conservatism that reduces absorption.

- Mass, Concentration: Solute saturation is assumed to be unlimited. Realistic saturation behavior is ignored in favor of showing the peak reactivity for the various materials regardless of concentration.
- Mass: Uranium oxide was modeled as UO_2. This molecule has the least number of oxygen atoms per uranium atom which will result in the highest reactivity when compared to other oxide compounds (i.e., UO_3 or U_3O_8).
- Geometry: For the determination of the subcritical limit for mass and volume, the most reactive geometry (a sphere) was used.
- Enrichment: Uranium is assumed to be enriched to 21 wt% ^{235}U, an increase over the nominal value of 19.75%.
- Reflection: For the mass and volume subcritical limits, the sphere was surrounded by 12 inches of close-fitting water reflection.
- Reflection: For the infinite uranyl sulfate solution concentration calculation, reflective boundary conditions were used on all sides to simulate an infinite amount of material.
- Moderation: Density of the uranium oxide and uranium metal were varied to determine the limiting conditions for NCS.
- Moderation: Uranyl sulfate is modeled assuming no excess acid as a conservative simplification. Excess acid will reduce moderation and increase neutron absorption.

RAI 6b.3-32

The NRC staff recalculated SHINE's upper safety limit (USL) using the USLSTATS code issued with the SCALE criticality code package. This recalculation produced a lower USL than that determined in Table 8 of SHINE's Validation Report. This difference in USL calculations appears to be the result of SHINE's use of a smaller single-sided lower tolerance limit factor, K, and pooled standard deviation, St, than those determined by USLSTATS. SHINE's tolerance limits factor is also smaller than the value listed in Table 2.1 of NUREG/CR-6698.*

Additional information is needed in order for the NRC staff to determine the adequacy of SHINE's USL calculation to resolve the discrepancy with NRC staff calculations. This information is necessary to demonstrate reasonable assurance that SHINE's final design will conform to its design bases with adequate margin for safety, as required by 10 CFR 50.34

Provide details of the USL calculations in Tables 6, 7, and 8 of SHINE's MNCP 6.1 Validation Report, Rev. 2, including the formulas used and references justifying them.

SHINE Response

In the SHINE validation report (Atkins-NS-DAC-SHN-15-03, Revision 2, provided as Attachment 4 to Enclosure 1 of Reference (6)), the 140 benchmark experiments were evaluated to determine if trends exist between the calculated k_{eff} and the following independent parameters: the hydrogen to fissile ratio (H/X), the Average Neutron Energy Causing Fission (ANECF), the ^{235}U enrichment, the moderator material, the reflector material, and the chemical form of the fissile material. SHINE determined that the calculated k_{eff} did not trend with any of these independent variables.

The ISG augmenting NUREG-1537, Part 2 (Reference 5) lists ANSI/ANS-8.24, as endorsed by Regulatory Guide 3.71 (Reference 7), as an acceptable validation methodology. ANSI/ANS-8.24-2007 (R2012) (Reference 8) references NUREG/CR-6698 (Reference 9) for details on calculating the upper safety limit (USL), such as statistical and nonstatistical methods and function fitting, computational margin determination, and justification for safety margin. The bias and bias uncertainty in the SHINE validation report were calculated using the equations listed in Section 2.4.1 of NUREG/CR-6698, which are also listed in Section 3.4.2 of the SHINE validation report.

After determining the data to be normal and displaying no trends, the single-sided tolerance limit was selected as the appropriate statistical treatment for determining the USL. This method uses the bias uncertainty (pooled standard deviation) and applies a single-sided lower tolerance factor (K* or U) based on the number of data points. Values for K* with 10 to 50 data points are listed in Table 2.1 of NUREG/CR-6698. NUREG/CR-6698 states that the K* value for 50 data points, 2.065, may be used as a conservative number for more than 50 data points. SHINE chose to use this K* value for the intermediate enriched uranium (IEU) USL data set (54 points), but chose to calculate the K* value for the other two data sets, when the number of data points significantly exceeded 50. The equations for calculating K* are listed below, and can also be found in Section 3.4.2 of the SHINE validation report. The equations are taken from Reference 9 of the SHINE validation report. Reference 9 of the SHINE validation report is the source of Table 2.1 of NUREG/CR-6698. The applicable pages of Reference 9 of the SHINE validation report are provided as Attachment 1.

$$K^* = \frac{z_P + \sqrt{z_P^2 - ab}}{a}$$

Where:

$$a = 1 - \frac{z_\gamma^2}{2(n-1)}$$

$$b = z_P^2 - \frac{z_\gamma^2}{n}$$

The Z_P and Z_γ values are the critical values from the normal distribution that is exceeded with specified probability (P = 95% and γ = 95%), and are both 1.645. The resulting K* values for the larger data sets in the SHINE validation report are 1.952 for the low enriched uranium (LEU) and IEU USL data set (84 points) and 1.877 for the combined LEU, IEU, and highly enriched uranium USL data set (140 points).

The pooled standard deviation (S_P) in NUREG/CR-6698 has two components, and is calculated according to Equation 6b.3-32-1.

$$S_P = \sqrt{s^2 + \bar{\sigma}^2} \qquad \text{Equation 6b.3-32-1}$$

For the single-sided tolerance limit method described in NUREG/CR-6698, these two components are the variance about the mean (s^2) and the average total uncertainty ($\bar{\sigma}$). They are calculated according to Equations 6b.3-32-2 through 6b.3-32-6.

$$s^2 = \frac{\left(\frac{1}{n-1}\right)\sum\frac{1}{\sigma_i^2}\left(k_{\text{eff}_i} - \bar{k}_{\text{eff}}\right)^2}{\frac{1}{n}\sum\frac{1}{\sigma_i^2}} \qquad \text{Equation 6b.3-32-2}$$

$$\bar{\sigma}^2 = \frac{n}{\sum\frac{1}{\sigma_i^2}} \qquad \text{Equation 6b.3-32-3}$$

With the normalized k_{eff} value for the "i^{th}" benchmark case,

$$k_{\text{eff}_i} = \frac{k_{\text{eff}_{calc_i}}}{k_{\text{eff}_{exp_i}}} \qquad \text{Equation 6b.3-32-4}$$

the uncertainty on the "i^{th}" k_{eff} value,

$$\sigma_i = \sqrt{\sigma_{calc_i}^2 + \sigma_{exp_i}^2} \qquad \text{Equation 6b.3-32-5}$$

and the weighted mean k_{eff}

$$\bar{k}_{\text{eff}} = \frac{\sum\frac{1}{\sigma_i^2}k_{\text{eff}_i}}{\sum\frac{1}{\sigma_i^2}} \qquad \text{Equation 6b.3-32-6}$$

Where:

- n = number of critical experiments in the validation
- $k_{\text{eff}_{exp_i}}$ = effective multiplication factor for the benchmark
- $k_{\text{eff}_{calc_i}}$ = effective multiplication factor for the calculation method
- σ_{exp_i} = uncertainty in the benchmark
- σ_{calc_i} = uncertainty in the calculation method

The pooled standard deviation is calculated differently in USLSTATS because a different statistical method is used. This method relies on there being a trend present in the data with a given independent variable. With no trend present in the data, the trend line determined by USLSTATS will have a poor fit. USLSTATS does not perform a "goodness of fit test" to determine how applicable this method is to the data set. The pooled standard deviation (S_P) for this method is a combination of the variance of the regression fit ($S_{k(x)}^2$) and the within-variance of the data (S_w^2).

$$S_P = \sqrt{S_{k(x)}^2 + S_w^2}$$ Equation 6b.3-32-7

$$S_{k(x)}^2 = \frac{1}{(n-2)}\left[\sum(k_{\text{eff}_i} - \bar{k}_{\text{eff}})^2 - \frac{\{\sum(x_i - \bar{x})(k_{\text{eff}_i} - \bar{k}_{\text{eff}})\}^2}{\sum(x_i - \bar{x})^2}\right]$$ Equation 6b.3-32-8

$$S_w^2 = \frac{1}{n}\sum \sigma_i^2$$ Equation 6b.3-32-9

Where:

- x_i = value for the independent variable associated with the "i[th]" k_{eff} value
- $\bar{x}$ = the mean value of parameter s in the set of calculations
- $\bar{k}_{\text{eff}}$ = the k_{eff} value for $\bar{x}$, calculated using the fitted function

In summary, USLSTATS calculates a different value for the pooled standard deviation because it uses a different statistical method, which relies on a trend being present in the data set. SHINE has determined that there is no trend in the validation data set and has used the single-sided tolerance limit method as described in NUREG/CR-6698.

RAI 6b.3-33

While Table 9, "Area of Applicability Summary," of the SHINE Validation Report, Rev. 2, includes cadmium, this material is not mentioned as present in Table 2, "Critical Benchmark Experiments Summary." Additionally, the discussion of some of the benchmark experiment sets mentions cadmium, but it is not clear if it is present in any of the experiments chosen from those benchmark sets.

Additional information is needed on SHINE's analysis of benchmark experiments in order for the NRC staff to assess the adequacy of SHINE's preliminary design.

Clarify whether the area of applicability (AOA) in the SHINE Validation Report, Rev. 2, includes cadmium as a neutron absorber.

SHINE Response

SHINE does not plan to use cadmium as a neutron absorber. Cadmium will be removed from Table 9 of the validation report during detailed design. An Issues Management Report (IMR) has been issued to track removing cadmium from Table 9 of the validation report during detailed design.

RAI 6b.3-34

As required by 10 CFR 50.34(a), "Contents of applications; technical information," a preliminary safety analysis report should include "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility..., and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents." Additionally, the preliminary design of the facility should provide reasonable assurance to the NRC staff that the final design will conform to its design bases with adequate margin for safety.

With respect to nuclear criticality control, the Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part that "[c]riticality process safety controls should be provided for criticality safety, and a description of their safety function should be described. The applicant should use enough safety controls to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical" and that "NCS [nuclear criticality safety] limits on controlled parameters will be established to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety."

The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states, in part, that the reviewer should determine "whether the margin of subcriticality for safety is sufficient to provide reasonable assurance of subcriticality."

In response to RAI 6b.3-4, SHINE states it intends to utilize a subcritical margin of 0.05 with additional considerations for uncertainty in the validation and modeling. In addition, SHINE states in multiple places in the PSAR that processes will be maintained to a keff ≤ 0.95 (assuming a subcritical margin of 0.05).

The NRC staff's review of SHINE's responses to RAIs 6b.3-1 and 6b.3-26 found that there was insufficient benchmarking of the code against experiments utilizing the materials and enrichments expected in SHINE's processes. For this reason, the proposed subcritical margin of 0.05 is not sufficient to adequately address the uncertainty associated with the neutron interactions of these process materials. The subcritical margin of 0.05, which SHINE quoted from NUREG-1520, was intended for facilities with enrichment less than five percent utilizing well established processes and for which there is significant experience and data. In contrast, the SHINE facility will be a first-of-a-kind facility using materials not normally utilized and of an enrichment up to 20 percent.

Provide additional information describing how SHINE has or will sufficiently benchmark against experiments utilizing the materials and enrichments expected to be used in SHINE facility processes for its proposed margin of subcriticality, or propose a new margin of subcriticality that appropriately takes into account materials and enrichment.

SHINE Response

The SHINE validation report, Atkins-NS-DAC-SHN-15-03, Revision 2, provided as Attachment 4 to Enclosure 1 of Reference (6), sufficiently benchmarks against experiments using materials and enrichments expected to be used in the SHINE facility processes. This report provides a proposed margin of subcriticality that appropriately takes into account materials and enrichment. It should be noted that one set of experiments (IEU-SOL-THERM-001) from the International

Criticality Safety Benchmark Evaluation Project (ICSBEP) Handbook was initially considered for use by SHINE in the validation process, but was ultimately determined to not be suitable for inclusion, as described below.

Benchmarks in the ICSBEP Handbook provide information on experimental data, uncertainty, and modeling information. In accordance with Regulatory Guide 3.71 (Reference 7), "the rejection of outliers should be based only on the inconsistency of the data with known physical behavior."

The IEU-SOL-THERM-001 set of experiments were performed at the Russian Research Center "Kurchatov Institute" in 1980-1981 to investigate nuclear safety issues for a special-purpose compact reactor and graphite reflector. During the review of the benchmark description, SHINE noted that sample calculation results from the Russian Federation indicated k_{eff} values that were significantly below (1.5% to 2.7%) the experimental k_{eff} values.

SHINE investigated this benchmark, and a comparison of the four IEU-SOL-THERM-001 benchmark cases with the modeling data has identified an inconsistency of the data with known physical behavior. Specifically, in the development of the Monte-Carlo N-Particle Transport Code (MCNP) models of IEU-SOL-THERM-001, SHINE noted that the calculated uranyl sulfate volume from the modeling information in the benchmark is approximately 3% less than the critical uranyl sulfate volumes specified in the benchmark description. Therefore, the data in the benchmark is physically inconsistent.

In addition, the ICSBEP Chairman agrees that there is an error in the sample calculations, which possibly indicates a more significant error in the benchmark model description. Per the ICSBEP Chairman, the current error would preclude it from being deemed an acceptable benchmark evaluation in the ICSBEP Handbook.

The ICSBEP is currently undergoing an investigation into the errors identified in IEU-SOL-THERM-001 with the intent of formally presenting the error and means to mitigate the problem, if possible. The ICSBEP Chairman stated that he does not recommend using IEU-SOL-THERM-001 to support validation efforts until the discrepancy has been corrected.

SHINE has determined that an error in the ICSBEP Handbook exists for the IEU-SOL-THERM-001 benchmark. This determination is based on inconsistency of the data with known physical behavior and the data should therefore be excluded in accordance with Regulatory Guide 3.71.

SHINE has sufficient benchmark cases covering the range of enrichments and materials in the SHINE facility, and has determined there are no trends in the bias with investigated parameters. The calculated USL will protect public health and safety. SHINE will consider any new or revised data pertinent to the criticality safety validation during final design. An IMR has been issued to track this action.

References

(1) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 26, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report (ML15239B051)

(2) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 27, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report

(3) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)

(4) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)

(5) U.S. Nuclear Regulatory Commission, "FINAL Interim Staff Guidance Augmenting NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," October 17, 2012 (ML12156A075)

(6) SHINE Medical Technologies, Inc. letter to NRC, dated July 23, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information 6b.3-30 (ML15222A231)

(7) U.S. Nuclear Regulatory Commission, "Nuclear Criticality Safety Standards for Fuels and Materials Facilities," Regulatory Guide 3.71, Revision 2, December 2010 (ML103210345)

(8) American National Standards Institute/American Nuclear Society, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations," ANSI/ANS-8.24-2007 (R2012), La Grange Park, IL

(9) U.S. Nuclear Regulatory Commission, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology," NUREG/CR-6698, January 2001 (ML050250061)

ENCLOSURE 1
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

APPLICABLE PAGES FROM NATIONAL BUREAU OF STANDARDS HANDBOOK 91

7 pages follow

UNITED STATES DEPARTMENT OF COMMERCE • Luther H. Hodges, *Secretary*

NATIONAL BUREAU OF STANDARDS • A. V. Astin, *Director*

Experimental Statistics

Mary Gibbons Natrella
National Bureau of Standards

Reprint of the Experimental Statistics Portion of the AMC Handbook

By permission of the Army Materiel Command

National Bureau of Standards Handbook 91

Issued August 1, 1963

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington 25, D.C.
Price $4.25

Procedure

Problem: If we are to make a simple series of measurements, how many measurements are required to estimate the standard deviation within P percent of its true value, with prescribed confidence?

(1) Specify P, the allowable percentage deviation of the estimated standard deviation from its true value.

(2) Choose γ, the confidence coefficient.

(3) In Figure 2-2, find P on the horizontal scale, and use the curve for the appropriate γ. Read on the vertical scale the required degrees of freedom.

(4) For a simple series of measurements, the required number is equal to one plus the degrees of freedom.

Example

Problem: How large a sample would be required to estimate the standard deviation within 20% of its true value, with confidence coefficient equal to 0.95?

(1) Let $P = 20\%$

(2) Let $\gamma = .95$

(3) For $\gamma = .95$, $P = 20\%$, the required degrees of freedom equals 46.

(4) $n = 46 + 1$
$= 47$

2-5 STATISTICAL TOLERANCE LIMITS

2-5.1 GENERAL

Sometimes we are more interested in the approximate *range* of values in a lot or population than we are in its average value. Statistical tolerance limits furnish limits between, above, or below which we confidently expect to find a prescribed proportion of individual items of the population. Thus, we might like to be able to give two values A and B between which we can be fairly certain that at least a proportion P of the population will lie, (two-sided limits), or a value A above which at least a proportion P will lie, (one-sided limit).

Thus for the data on thickness of mica washers (Data Sample 2-1), we could give two thickness values, stating with chosen confidence that a proportion P (at least) of the washers in the lot have thicknesses between these two limits. We call the confidence coefficient γ, and it refers to the proportion of the time that our method will result in correct statements. If a normal distribution can be assumed, use the procedures of Paragraphs 2-5.2 and 2-5.3; otherwise use the procedures of Paragraph 2-5.4.

2-5.2 TWO-SIDED TOLERANCE LIMITS FOR A NORMAL DISTRIBUTION

When the mean m and standard deviation σ of a normally distributed quantity are known, symmetrical limits that include a prescribed proportion P of the distribution are readily obtained by adding and subtracting $z_\alpha \sigma$ from the known mean m, where z_α is read from Table A-2 with $\alpha = \frac{1}{2}(P+1)$. When m and σ are not known, we can use an interval of the form $\bar{X} \pm Ks$. Since both $\bar{X}$ and s will vary from sample to sample it is impossible to determine K so that the limits $\bar{X} \pm Ks$ will always include a specified proportion P of the underlying normal distribution. It is, however, possible to determine K so that in a long series of samples from the same or different normal distributions a definite proportion γ of the intervals $\bar{X} \pm Ks$ will include P or more of the underlying distribution(s).

Procedure

Problem: We would like to state two limits between which we are 100 γ percent confident that 100 P percent of the values lie.

(1) Choose P, the proportion, and γ, the confidence coefficient.

(2) Compute from the sample:
$\bar{X}$
s

(3) Look up K for chosen P and γ in Table A-6.

(4) Compute:
$X_U = \bar{X} + Ks$

$X_L = \bar{X} - Ks$

Conclude: With 100 γ % confidence we may predict that a proportion P of the individuals of the population have values between X_L and X_U.

Example

Problem: We would like to state thickness limits between which we are 95% confident that 90% of the values lie (Data Sample 2-1).

(1) Let $P = .90$
$\gamma = .95$

(2)
$\bar{X} = .1260$ inch
$s = 0.00359$ inch

(3) $K = 2.839$

(4)
$X_U = .1260 + 2.839\ (.00359)$
$= 0.136$ inch
$X_L = .1260 - 2.839\ (.00359)$
$= 0.116$ inch

Conclude: With 95% confidence, we may say that 90% of the washers have thicknesses between 0.116 and 0.136 inch.

2-5.3 ONE-SIDED TOLERANCE LIMITS FOR A NORMAL DISTRIBUTION

Sometimes we are interested only in estimating a value above which, or below which, a proportion P (at least) will lie. In this case the one-sided upper tolerance limit will be $X_U = \bar{X} + Ks$; and $X_L = \bar{X} - Ks$ will be the one-sided lower limit. The appropriate values for K are given in Table A-7 and are not the same as those of Paragraph 2-5.2.

Procedure

Problem: To find a single value above which we may predict with confidence γ that a proportion P of the population will lie.

(1) Choose P the proportion and γ, the confidence coefficient.

(2) Compute:
$\bar{X}$
s

(3) Look up K in Table A-7 for the appropriate n, γ, and P.

(4) $X_L = \bar{X} - Ks$

Example

Problem: To find a single value above which we may predict with 90% confidence that 99% of the population will lie. (Data Sample 2-1).

(1) Let $P = .99$
$\gamma = .90$

(2)
$\bar{X} = .1260$ inch
$s = 0.00359$ inch

(3) $K\ (10, .90, .99) = 3.532$

(4) $X_L = .1260 - 3.532\ (.00359)$
$= .1133$ inch

Thus we are 90% confident that 99% of the mica washers will have thicknesses above .113 inch.

Note: Factors for some values of n, γ, and P not covered in Table A-7 may be found in Sandia Corporation Monograph SCR-13[2]. Alternatively, one may compute K using the following formulas:

$$a = 1 - \frac{z_\gamma^2}{2(n-1)}$$ (where z can be found in Table A-2)

$$b = z_P^2 - \frac{z_\gamma^2}{n}$$

$$K = \frac{z_P + \sqrt{z_P^2 - ab}}{a}$$

2-5.4 TOLERANCE LIMITS WHICH ARE INDEPENDENT OF THE FORM OF THE DISTRIBUTION

The methods given in Paragraphs 2-5.2 and 2-5.3 are based on the assumption that the observations come from a normal distribution. If the distribution is not in fact normal, then the effect will be that the true proportion P of the population between the tolerance limits will vary from the intended P by an amount depending on the amount of departure from normality. If the departure from normality is more than slight we can use a procedure which assumes only that the distribution has no discontinuities. The tolerance limits so obtained will be substantially wider than those assuming normality.

2-5.4.1 Two-Sided Tolerance Limits (Distribution-Free)

Table A-30 gives values (r, s) such that we may assert with confidence at least γ that $100P\%$ of a population lies between the r^{th} smallest and the s^{th} largest of a random sample of n from that population. For example, from Table A-30 with $\gamma = .95$, $P = .75$, and $n = 60$, we may say that if we have a sample of $n = 60$, then we may have a confidence of at least $\gamma = .95$ that $100P\% = 75\%$ of the population will lie between the fifth largest $(s = 5)$ and the fifth smallest $(r = 5)$ of the sample values. That is, if we were to take many random samples of 60, and take the fifth largest and fifth smallest of each, we should expect to find that at least 95% of the resulting intervals would contain 75% of the population.

Table A-32 may be useful for sample sizes of $n \leq 100$. This table gives the confidence γ with which we may assert that $100P\%$ of the population lies between the largest and smallest values of the sample.

2-5.4.2 One-Sided Tolerance Litmits (Distribution-Free)

Table A-31 gives the largest value of m such that we may assert with confidence at least γ that $100P\%$ of a population lies below the m^{th} largest (or above the m^{th} smallest) of a random sample of n from that population. For example, from Table A-31 with $\gamma = .95$, $P = .90$, and $n = 90$, we may say that we are 95% confident that 90% of a population will lie below the fifth largest value of a sample of size $n = 90$.

REFERENCES

1. M. G. Kendall and W. R. Buckland, *A Dictionary of Statistical Terms,* p. 79, Oliver and Boyd, London, 1957.
2. D. B. Owen, *Table of Factors for One-Sided Tolerance Limits for a Normal Distribution,* Sandia Corporation Monograph SCR-13, April 1958.

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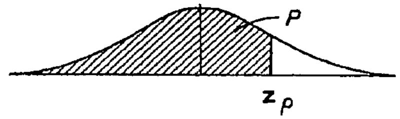
TABLE A-2. CUMULATIVE NORMAL DISTRIBUTION—VALUES OF z_P



Values of z_P corresponding to P for the normal curve.

z is the standard normal variable

P	.00	.01	.02	.03	.04	.05	.06	.07	.08	.09
.00	—	−2.33	−2.05	−1.88	−1.75	−1.64	−1.55	−1.48	−1.41	−1.34
.10	−1.28	−1.23	−1.18	−1.13	−1.08	−1.04	−0.99	−0.95	−0.92	−0.88
.20	−0.84	−0.81	−0.77	−0.74	−0.71	−0.67	−0.64	−0.61	−0.58	−0.55
.30	−0.52	−0.50	−0.47	−0.44	−0.41	−0.39	−0.36	−0.33	−0.31	−0.28
.40	−0.25	−0.23	−0.20	−0.18	−0.15	−0.13	−0.10	−0.08	−0.05	−0.03
.50	0.00	0.03	0.05	0.08	0.10	0.13	0.15	0.18	0.20	0.23
.60	0.25	0.28	0.31	0.33	0.36	0.39	0.41	0.44	0.47	0.50
.70	0.52	0.55	0.58	0.61	0.64	0.67	0.71	0.74	0.77	0.81
.80	0.84	0.88	0.92	0.95	0.99	1.04	1.08	1.13	1.18	1.23
.90	1.28	1.34	1.41	1.48	1.55	1.64	1.75	1.88	2.05	2.33

Special Values

P	.001	.005	.010	.025	.050	.100
z_P	−3.090	−2.576	−2.326	−1.960	−1.645	−1.282

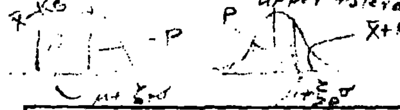
P	.999	.995	.990	.975	.950	.900
z_P	3.090	2.576	2.326	1.960	1.645	1.282

TABLE A-7. FACTORS FOR ONE-SIDED TOLERANCE LIMITS FOR NORMAL DISTRIBUTIONS

Factors K such that the probability is γ that at least a proportion P of the distribution will be less than $\bar{X} + Ks$ (or greater than $\bar{X} - Ks$), where $\bar{X}$ and s are estimates of the mean and the standard deviation computed from a sample size of n. see p 2-14

	$\gamma = 0.75$					$\gamma = 0.90$				
n \ P	0.75	0.90	0.95	0.99	0.999	0.75	0.90	0.95	0.99	0.999
3	1.464	2.501	3.152	4.396	5.805	2.602	4.258	5.310	7.340	9.651
4	1.256	2.134	2.680	3.726	4.910	1.972	3.187	3.957	5.437	7.128
5	1.152	1.961	2.463	3.421	4.507	1.698	2.742	3.400	4.666	6.112
6	1.087	1.860	2.336	3.243	4.273	1.540	2.494	3.091	4.242	5.556
7	1.043	1.791	2.250	3.126	4.118	1.435	2.333	2.894	3.972	5.201
8	1.010	1.740	2.190	3.042	4.008	1.360	2.219	2.755	3.783	4.955
9	0.984	1.702	2.141	2.977	3.924	1.302	2.133	2.649	3.641	4.772
10	0.964	1.671	2.103	2.927	3.858	1.257	2.065	2.568	3.532	4.629
11	0.947	1.646	2.073	2.885	3.804	1.219	2.012	2.503	3.444	4.515
12	0.933	1.624	2.048	2.851	3.760	1.188	1.966	2.448	3.371	4.420
13	0.919	1.606	2.026	2.822	3.722	1.162	1.928	2.403	3.310	4.341
14	0.909	1.591	2.007	2.796	3.690	1.139	1.895	2.363	3.257	4.274
15	0.899	1.577	1.991	2.776	3.661	1.119	1.866	2.329	3.212	4.215
16	0.891	1.566	1.977	2.756	3.637	1.101	1.842	2.299	3.172	4.164
17	0.883	1.554	1.964	2.739	3.615	1.085	1.820	2.272	3.136	4.118
18	0.876	1.544	1.951	2.723	3.595	1.071	1.800	2.249	3.106	4.078
19	0.870	1.536	1.942	2.710	3.577	1.058	1.781	2.228	3.078	4.041
20	0.865	1.528	1.933	2.697	3.561	1.046	1.765	2.208	3.052	4.009
21	0.859	1.520	1.923	2.686	3.545	1.035	1.750	2.190	3.028	3.979
22	0.854	1.514	1.916	2.675	3.532	1.025	1.736	2.174	3.007	3.952
23	0.849	1.508	1.907	2.665	3.520	1.016	1.724	2.159	2.987	3.927
24	0.845	1.502	1.901	2.656	3.509	1.007	1.712	2.145	2.969	3.904
25	0.842	1.496	1.895	2.647	3.497	0.999	1.702	2.132	2.952	3.882
30	0.825	1.475	1.869	2.613	3.454	0.966	1.657	2.080	2.884	3.794
35	0.812	1.458	1.849	2.588	3.421	0.942	1.623	2.041	2.833	3.730
40	0.803	1.445	1.834	2.568	3.395	0.923	1.598	2.010	2.793	3.679
45	0.795	1.435	1.821	2.552	3.375	0.908	1.577	1.986	2.762	3.638
50	0.788	1.426	1.811	2.538	3.358	0.894	1.560	1.965	2.735	3.604

TABLE A-7 (Continued). FACTORS FOR ONE-SIDED TOLERANCE LIMITS FOR NORMAL DISTRIBUTIONS



	γ = 0.95					γ = 0.99				
n \ P	0.75	0.90	0.95	0.99	0.999	0.75	0.90	0.95	0.99	0.999
3	3.804	6.158	7.655	10.552	13.857	—	—	—	—	—
4	2.619	4.163	5.145	7.042	9.215	—	—	—	—	—
5	2.149	3.407	4.202	5.741	7.501	—	—	—	—	—
6	1.895	3.006	3.707	5.062	6.612	2.849	4.408	5.409	7.334	9.540
7	1.732	2.755	3.399	4.641	6.061	2.490	3.856	4.730	6.411	8.348
8	1.617	2.582	3.188	4.353	5.686	2.252	3.496	4.287	5.811	7.566
9	1.532	2.454	3.031	4.143	5.414	2.085	3.242	3.971	5.389	7.014
10	1.465	2.355	2.911	3.981	5.203	1.954	3.048	3.739	5.075	6.603
11	1.411	2.275	2.815	3.852	5.036	1.854	2.897	3.557	4.828	6.284
12	1.366	2.210	2.736	3.747	4.900	1.771	2.773	3.410	4.633	6.032
13	1.329	2.155	2.670	3.659	4.787	1.702	2.677	3.290	4.472	5.826
14	1.296	2.108	2.614	3.585	4.690	1.645	2.592	3.189	4.336	5.651
15	1.268	2.068	2.566	3.520	4.607	1.596	2.521	3.102	4.224	5.507
16	1.242	2.032	2.523	3.463	4.534	1.553	2.458	3.028	4.124	5.374
17	1.220	2.001	2.486	3.415	4.471	1.514	2.405	2.962	4.038	5.268
18	1.200	1.974	2.453	3.370	4.415	1.481	2.357	2.906	3.961	5.167
19	1.183	1.949	2.423	3.331	4.364	1.450	2.315	2.855	3.893	5.078
20	1.167	1.926	2.396	3.295	4.319	1.424	2.275	2.807	3.832	5.003
21	1.152	1.905	2.371	3.262	4.276	1.397	2.241	2.768	3.776	4.932
22	1.138	1.887	2.350	3.233	4.238	1.376	2.208	2.729	3.727	4.866
23	1.126	1.869	2.329	3.206	4.204	1.355	2.179	2.693	3.680	4.806
24	1.114	1.853	2.309	3.181	4.171	1.336	2.154	2.663	3.638	4.755
25	1.103	1.838	2.292	3.158	4.143	1.319	2.129	2.632	3.601	4.706
30	1.059	1.778	2.220	3.064	4.022	1.249	2.029	2.516	3.446	4.508
35	1.025	1.732	2.166	2.994	3.934	1.195	1.957	2.431	3.334	4.364
40	0.999	1.697	2.126	2.941	3.866	1.154	1.902	2.365	3.250	4.255
45	0.978	1.669	2.092	2.897	3.811	1.122	1.857	2.313	3.181	4.168
50	0.961	1.646	2.065	2.863	3.766	1.096	1.821	2.296	3.124	4.096