DESIGNATED ORIGINAL

PDR

SECRETARIAT—ANSI COMMITTEE N13 (RADIATION PROTECTION)

JOHN W. POSTON, PH.D.
CHAIRMAN, ANSI COMMITTEE N13
SCHOOL OF NUCLEAR ENGINEERING
GEORGIA INSTITUTE OF TECHNOLOGY
ATLANTA, GA 30332
(404) 894-3724

RICHARD J. BURK, JR.
SECRETARY, ANSI COMMITTEE N13
4720 MONTGOMERY LANE, SUITE 506
BETHESDA, MD 20014
(301) 654-3060

OP-713-4

MEMORANDUM

DATE: October 15, 1979

TO: N13.14 Voters

FROM: John W. Poston, N13 Chairman JWP

SUBJ: N13.14 (formerly N721)

In accordance with ANSI procedure 4.12.5, enclosed please find an unresolved negative N13.14 (was N721) ballot with comments as submitted by the EPA representative, R.H. Johnson, Jr. In addition, copies of affirmative ballots with comments are enclosed. Please review all these materials and, after careful consideration, notify N13 in Bethesda if you wish to change your vote to negative. Please note that the prescribed time period for this action is 30 days (rather than the usual 60-day period), therefore November 15 is the deadline for receipt in Bethesda.

This is an important standard. I again request that each of you give all the comments careful consideration.

JWP/mjmc
cc: Bryce L. Rich, HPSSC Chairman
MaryJo McCarrick, N13 Staff Assistant
Mary Vaca, ANSI

(1)

LETTER BALLOT

ANSI COMMITTEE N13

Topic: Final Approval of Proposed Standard N721

Internal Dosimetry Standards for Tritium

Authorized By: John W. Poston, N13 Chairman

Distributed By: MaryJo McCarrick, N13 Staff Assistant, on June 5, 1979

RETURN TO: Health Physics Society, 4720 Montgomery Lane, Bethesda, MD 20014

DUE DATE: August 6, 1979

SHALL THE N13 COMMITTEE RECOMMEND TO THE BOARD OF STANDARDS REVIEW THAT THE REVISED PROPOSED STANDARD N721 BE APPROVED AS AN AMERICAN NATIONAL STANDARD?

I Vote: (✓) Yes ( ) No* ( ) Abstain*

Name JW Poston Signature John W. Poston

Print or Type

Organization Represented N13 Date Oct 5, 1979

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over):

see attached comments + J. Auxier

FOR INFORMATION

John Poston — Hal Butler

If I could vote on this, I do — here is what I would do — and we feel strongly about this — is in my office now. John

FOR INFORMATION

LETTER BALLOT
ANSI COMMITTEE N13

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I Vote: ( ) Yes (X) No* ( ) Abstain*

Name JOHN A. Auxier Signature J. A. Auxier
Print or Type

Organization Represented ORNL Date June 20, 79

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over):

Values in table one are too high for Tritiated Water for Bench-top operations. Caveats notwithstanding, the obvious conclusion of those desiring such operations is that it is O.K. to operate w/o surveillance on the bench — The Level for tritiated water on the bench should be lowered by at least a factor of 10.

JAA

LETTER BALLOT

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I Vote: (X) Yes) No* ( ) Abstain*

Name LARRY A. CROSS Signature [signature]
Print or Type

Organization Represented [illegible] Date 6/23/79

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over): See comment sheet.

COMMENT ON DRAFT N721

In Appendix C, page 28, 3rd paragraph, the meaning of one sentence is not clear.

If the intent is,

(H_C estimated from absorbed HTO) > 90% total H_C, then I propose:

"....However, the dose equivalent to the whole body estimated from absorbed tritiated water following an acute exposure to tritiated water is generally considered to be at least 90% of the total committed dose equivalent."

If the intent is,

(H_C due to absorbed HTO) > 90% total H_C, then I propose:

"....However, the committed dose equivalent from absorbed tritiated water is generally considered to be at least 90% of the total committed dose equivalent to the whole body."

RECEIVED

AUG 10 1979

LETTER BALLOT

ANSI COMMITTEE N13

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Internal Dosimetry Standards for Tritium

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DUE DATE: August 6, 1979

SHALL THE N13 COMMITTEE RECOMMEND TO THE BOARD OF STANDARDS REVIEW THAT THE REVISED PROPOSED STANDARD N721 BE APPROVED AS AN AMERICAN NATIONAL STANDARD?

I Vote: (X) Yes ( ) No* ( ) Abstain*

Name Marvin K Sullivan Signature Marvin K. Sullivan
Print or Type

Organization Represented Edison Electric Institute Date 8-2-79

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over):

See Attached

PACIFIC GAS AND ELECTRIC COMPANY

77 BEALE STREET • SAN FRANCISCO, CALIFORNIA 94106 • (415) 781-4211 • TWX 910-372-6587

July 3, 1979

Mr. James E. Sohngen
Edison Electric Institute
1140 Connecticut Avenue, N.W.
Washington, D.C. 20036

Dear Mr. Sohngen:

I have the following comments on the proposed Standard ANSI N721, "Internal Dosimetry Standards for Tritium."

1. Paragraph 6.3.4 - should be eliminated. Reason: unnecessary and confusing.

2. Paragraph 6.3 - should be modified as follows "...bioassay program required by the criteria of Section 5 to assure..." New wording is underlined. Reason: clarity.

3. Paragraph 6.3.5 - insert "conducted" after "...shall be..." Reason: clarity.

4. Paragraph 6.4 - "Diagnostic bioassay". This type of bioassay should be defined in Section 4. Is a "diagnostic bioassay" any different than a "routine bioassay" or is it just performed more frequently?

5. Paragraph 8.8 - How is the individual to produce a sample thereafter? Suggest rewording.

   Also, is it reasonable to assume that tritium concentration in the urine within one hour of exposure is representative of the average concentration in body water? A far better sample would be a specimen from the morning voiding the day after the suspected exposure.

6. Section 8 - takes a lot of verbage to cover relatively little ground. For instance, I believe the first two sentences of Paragraph 8.13 could be eliminated with no loss of comprehension.

Also, are Paragraphs 8.4 and 8.5 really necessary? Perhaps they are misplaced and should be in Appendix B.

7. Paragraph 10.1.2 - third sentence change "Table 10" to "Table 2."

If there are any questions, please feel free to call.

Sincerely,

Thomas A. Jenckes
Radiation Protection Advisor

TAJ:saw

RECEIVED

AUG 6 1979

LETTER BALLOT

ANSI COMMITTEE N13

Topic: Final Approval of Proposed Standard N721

Internal Dosimetry Standards for Tritium

Authorized By: John W. Poston, N13 Chairman

Distributed By: MaryJo McCarrick, N13 Staff Assistant, on June 5, 1979

RETURN TO: Health Physics Society, 4720 Montgomery Lane, Bethesda, MD 20014

DUE DATE: August 6, 1979

SHALL THE N13 COMMITTEE RECOMMEND TO THE BOARD OF STANDARDS REVIEW THAT THE REVISED PROPOSED STANDARD N721 BE APPROVED AS AN AMERICAN NATIONAL STANDARD?

I Vote: (X) Yes ( ) No* ( ) Abstain*

Name Harry F. Schulte Signature _____
Print or Type

Organization Represented NCRP Date Aug. 1, 1979

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over):

I think this is a very good standard and hence have voted in favor of adoption. As a recent addition to the N13 Committee I do have a few comments which I would appreciate having passed on to the Committee who wrote it. On page 4, paragraph 4.2 I don't like the term "quanity of radioactivity". This implies that radioactivity is a thing when it is really a process.

I cannot really understand paragraph 8.8

In paragraph 8.10 the term "standard error" is used. This is really an ill-defined term and if "standard deviation" is meant that term should be used. Actually, since the result is expressed in percent it should be "relative standard deviation" or "coefficient of varation."

over

In appendix A, last sentence of third paragraph.- The wording "Hood is judged to give 10X the protection" is somewhat unclear. 10X the protection of what? It really means thatit assumes that the hood will reduce the uptake to 0.1 or it reduces the uptake by a factor of.10 below that assumed where no hood is used.

These comments are merely points of clarification and not of substance and that is why I voted in favor of adoption.

10

RECEIVED

JUL 9 1979

LETTER BALLOT

ANSI COMMITTEE N13

Topic: Final Approval of Proposed Standard N721

Internal Dosimetry Standards for Tritium

Authorized By: John W. Poston, N13 Chairman

Distributed By: MaryJo McCarrick, N13 Staff Assistant, on June 5, 1979

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DUE DATE: August 6, 1979

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I Vote: (X) Yes ( ) No* ( ) Abstain*

Name T. P. Loftus Signature T. P. Loftus
Print or Type

Organization Represented Dosimetry Group, Nat. Bur. of Standards Date July 3, 1979

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over):

p. 4 The term "Dose Equivalent" should be defined.

p. 5 5.1 This is very difficult to understand, perhaps because the last sentence contains about sixty words.

Shouldn't terms be defined before they are used. Why should it be necessary to look in section 6 for the definition of a term used in section 5.

How can the preparatory bioassay which is a "base line" measurement affect the uncertainty in estimating the total dose equivalent.

p. 7 I don't understand the need for the "Quantities tabulated are:".

p. 9 The last sentence implies that the committed dose equivalent is reduced by repeated measurements.

Continued

p. 12 8.8 . . . "and produce a sample thereafter."?
This phrase should be clarified or deleted.

p. 13 9.2 This part is very difficult to read and understand. It sounds as if one estimates an upper limit to the dose equivalent in order to choose a method for estimating the dose equivalent. It sounds bootstrappy.

In the last sentence it reads as if you receive a dose from the bioassay results.

p. 14 9.4, line 4. Is it the accuracy of the method that is to be confirmed or the method itself?

9.5 Definition of Hc should read, " . . . equivalent calculated from . . . "

p. 15 9.6 Equations 1 and 2 are inconsistent.

The rest of the standard appears to be in good shape, although I have the same problem with paragraph 3 in Appendix C as I had with section 9.2.

I have not checked the equations after Eq. 1 and 2; I will leave that to those who are expert in this field.

11

12

RECEIVED

AUG 10 1979

LETTER BALLOT

ANSI COMMITTEE N13

Topic: Final Approval of Proposed Standard N721

Internal Dosimetry Standards for Tritium

Authorized By: John W. Poston, N13 Chairman

Distributed By: MaryJo McCarrick, N13 Staff Assistant, on June 5, 1979

RETURN TO: Health Physics Society, 4720 Montgomery Lane, Bethesda, MD 20014

DUE DATE: August 6, 1979

SHALL THE N13 COMMITTEE RECOMMEND TO THE BOARD OF STANDARDS REVIEW THAT THE REVISED PROPOSED STANDARD N721 BE APPROVED AS AN AMERICAN NATIONAL STANDARD?

I Vote: ( ) Yes (✓) No* ( ) Abstain*

Name Raymond H. Johnson, Jr. Signature Raymond H. Johnson, Jr.
Print or Type

Organization Represented U.S. Environmental Protection Agency Date Aug. 2, 1979

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over):

(See attached comments).

RAYMOND H. JOHNSON, JR.

U.S. ENVIRONMENTAL PROTECTION AGENCY

(13)

Stephen T. Bard

Comments on ANSI-N721 Standard

Internal Dosimetry Standards for Tritium

General Comments

These standards are developed on the premise that tritium (HTO) is eliminated from the body with a ten day half-time. Since approximately 33% of the body hydrogen is associated with an organic fraction and it has been determined that there are two long-term compartments, some attempt should be made to account for this in the standard. This could be accomplished by using a simple three component exponential model for acute exposures and a specific activity approach for chronic intake. If the committee feels that this unecessarily complicates the method, then the additional dose commitment from organic labeling could be accounted for by increasing the quality factor by an appropriate value.

In its present form, the dose model, which is based upon bioassay data, will always result in an underestimate of the dose commitment.

Specific Comments

Section 9.0 Interpretation of Bioassay Results.

Equations 1 and 2 of Section 9.6 provide an estimate of the whole body dose commitment to body water from an acute intake of tritium. It does not, however, consider the dose received to tissues due to organic labeling from HTO.

Consider an acute ^{3}H intake resulting in a urine sample containing 10 Ci/liter (C_o). The predicted dose commitment from equation 2 ($C_{T=0}$) would be:

$$H = 4.2\ (10\ \mu Ci/liter)$$

$$H = 42\ mrem$$

In order to compare this to the dose commitment from organic tritium this may be rearranged into the integral form:

$$\frac{10\ \mu Ci - days}{1\ kg(0.069)} \simeq 145\ \frac{\mu Ci - days}{kg}$$

T-1/2 = 10 days

1 liter = 1 kg

The kinetics of organic tritium labeling from acute HTO body water burdens.

It has been determined from the work of Snyder (Sn-68), Sanders and Reinig (Sa-65) and Bennett (Be-72) that hydrogen from body water is incorporated into two relatively long term hydrogen pools with half times of about 45 days and 400 days at the rate of about 0.055 liters (H_2O) and 0.01 liter (H_2O) day respectively.

At equilibrium, these two pools would consist of about 1000 gms of hydrogen derived directly from body water.

$$Q_2 = \frac{0.055 \text{ liters } H_2O}{\text{day}} \times \frac{111 \text{ gH}}{\text{liter}} \times \frac{45 \text{ days}}{0.693} = 400 \text{ gH}$$

$$Q_3 = \frac{0.01 \text{ liters } (H_2O)}{\text{day}} \times \frac{111 \text{ gH}}{\text{liter}} \times \frac{400 \text{ days}}{.693} = 640 \text{ gH}$$

Total 1040 gH

The uptake of ^3H into these two compartments from a 10 µCi/liter acute body water burden concentration would be calculated as follows:

$$\frac{10 \text{ µCi}}{\text{liter} \times 0.069 \text{ day}^{-1}} = \frac{145 \text{ µCi - day}}{\text{liter}}$$

Then:

$$Q_2 = \frac{145\ \mu Ci - day}{liter} \times \frac{0.055\ liter}{day} = 8.0\ \mu Ci$$

$$Q_3 = \frac{145\ \mu Ci - day}{liter} \times \frac{0.01\ liter}{day} = 1.45\ \mu Ci$$

Estimated "tissue" dose

These two long-term compartments are not likely to tissue specific, however, if we consider tissue to be 10% hydrogen by weight, the associated tissue mass would be:

Q_2 = 400 gm H/0.10 = 4.0 kg tissue

Q_3 = 640 g H/0.10 = 6.4 kg tissue

The time integrated activity would then be:

$$Q_2 = \frac{8\ Ci}{4.0\ kg} \times \frac{45\ days}{.693} = \frac{133\ \mu Ci\text{-days}}{kg}$$

$$Q_3 = \frac{1.45\ Ci}{6.4\ kg} \times \frac{400\ days}{.693} = \frac{130\ \mu Ci\text{-days}}{kg}$$

Labile Hydrogen

It was estimated that there are about 1000 gms of hydrogen associated with the two long-term compartments. Since there are about 2400 gms of organic hydrogen in the body we can make the conservative assumption that 1400 gms H(2400-1000) are in labile positions and readily exchange with H_2O (or HTO). The dose commitment of this 4th compartment is:

$$\frac{10\ \mu Ci\ \text{liter}\ (H_2O) \times 1400\ gH}{\text{Liter} \times 111 gH} = 126\ \mu Ci$$

$$1400 gH / 0.10 = 14\ kg\ \text{tissue}$$

$$T\ 1/2 = 10\ \text{days}$$

$$Q_4 = \frac{126\ \mu Ci}{14\ kg} \times \frac{10\ \text{days}}{.693} = 130\ \frac{\mu Ci\text{-days}}{kg}$$

In summary each of the four hydrogen comparments would recieve about the same dose commitment:

$$Q_1 = 145\ \frac{\mu Ci\text{-days}}{kg} = 40\ \text{mrem}$$

$Q_2 = 133$ " " $= 40$ "

$Q_3 = 130$ " " $= 40$ "

$Q_4 = 130$ " " $= 40$ "

Total 160 mrem

It seems, therefore, that the dosimetry of tritium in the body is not quite as simple as it appears and that the use of a one compartment model will always understimate dose commitments even from acute intakes of tritium.

Section 9.6

Equation 1 calculates the dose equivalent (4) between bioassay samples while the action guides appear to be based upon the infinite

dose commitment. It might be advisable, therefore, to insert an equation (1.5) between 1 and 2 for calculating the total dose commitment when C_T does not equal zero.

$$H = \frac{0.3\ C_o\ (1-e^{-kT})}{R} \qquad \text{(eq. 1.5)}$$

where: $k = \frac{\ln C_o / C_T}{T}$

9.4 2 uCi/liter Zero Cutoff.

The use of a 2 uCi/liter zero cutoff contradicts the action guide lines established in Table 2. A chronic 2 uCi/liter body water burden is about 10% of the present maximum occupational limit with an associated dose rate of 0.5 rem/year. It would therefore appear permissible to allow a chronic dose rate of 0.5 rem/year to go unrecorded while an acute dose commitment of 0.5 rem requires some remedial action.

A zero cutoff should be eliminated or reduced to a limit where it does not conflict with the action level guides.

10.1.1 For Purposes of Preparatory Evaluation

This section states that the previous radiation history of new employees will be reviewed and that this will include the results of new bioassay data. The kinetics given in Section 9.0, however, are not sufficient to evaluate dose commitments for some former tritium workers returning to the industry.

Figure 1 is a long-term tritium excretion curve from a former tritium worker. Sampling was initiated about six months following termination of employment. A specific activity model from the results of the first sample (0.055 uCi/ℓ) would indicate a body burden of:

0.055 uCi/liter x 43 liters = 2.4 uCi

The actual body burden at t = 0 is, however,:

$$Q_3 = \frac{0.055 \text{ uCi/l} \times 3 \text{ l/day}}{0.002 \text{ day}^{-1}}$$

$$Q_3 = 83 \text{ uCi}$$

It was calculated in the previous section that this long-term component (Q_3) was associated with about 6.4 kg of tissue so that the time integrated unit weight concentration would be:

$$\frac{83 \text{ uCi day}}{6.4 \text{ kg } .002} = 6500 \frac{\text{uCi - day}}{\text{kg}}$$

This is significantly higher than if it were assumed that 2.4 uCi were distributed equally throughout 43 kg of water with a 10 day half-time:

$$\frac{2.4 \text{ uCi day}}{43 \text{ kg } .0693} = 0.8 \frac{\text{uCi - day}}{\text{kg}}$$

It is thus possible to underestimate a unit tissue dose by a factor of 8000 in this instance.

References

1. (Sn-68) W. S. Snyder et al. "Urinary Excretion of Tritium Following Exposure to Man to HTO - A Two Exponential Model," Physics in Medicine and Biology, 13, 547-559 (1968).

2. (Sa-65) Sanders, S. M. and Reinig, W. C. "Assessment of Tritium in Man," "Proceedings of Diagnosis and Treatment of Deposited Radionuclide Symposium," Richland, Washington, May 1965.

3. (Be-72) B. G. Bennett. "The Radiation Dose Due to the Acute Intake of Tritium by Man," HASL, 1972.

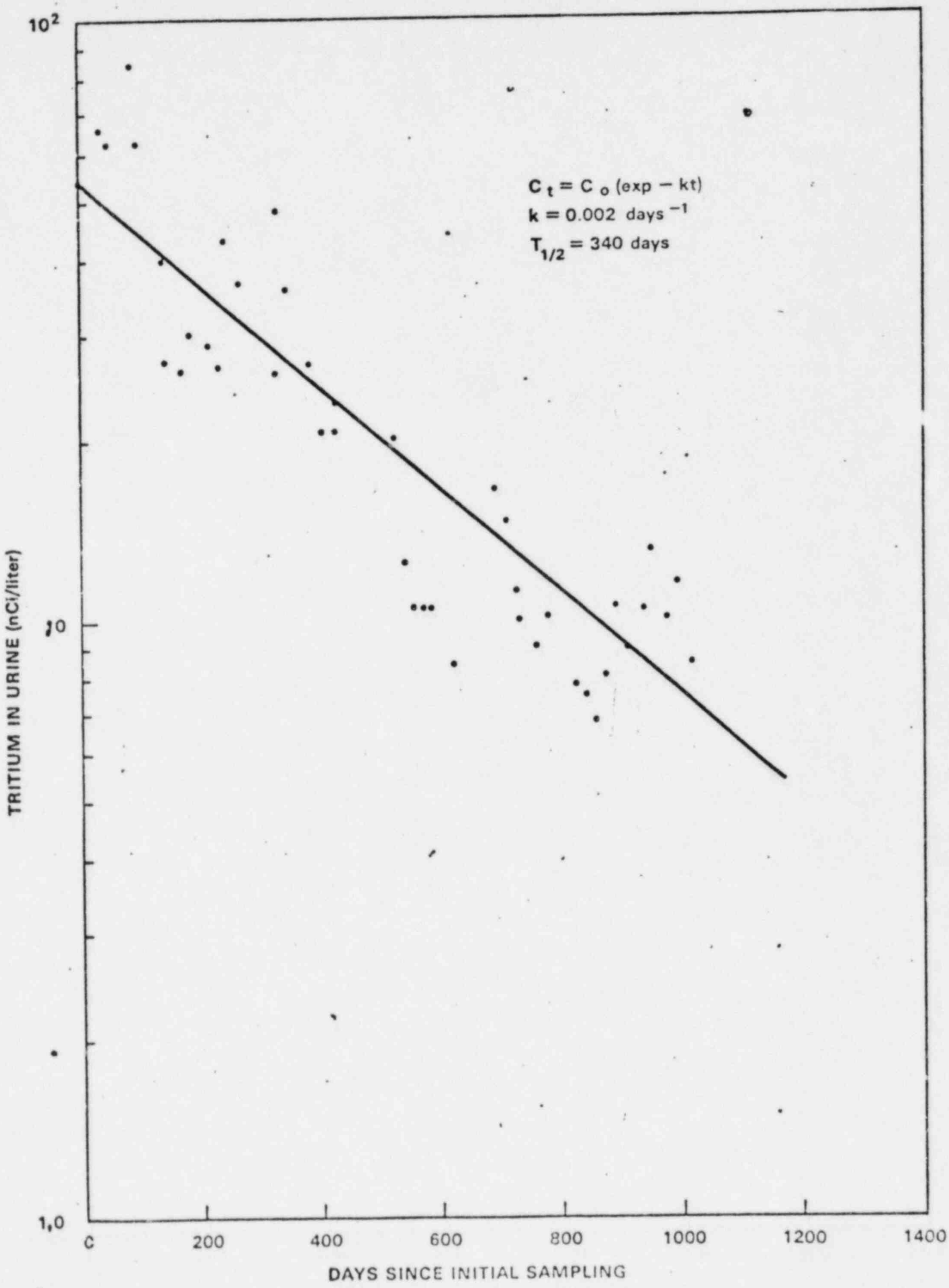

FIGURE 1 LONG TERM TRITIUM EXCRETION DATA (MOGHISSI 1978)

LETTER BALLOT

ANSI COMMITTEE N13

Topic: Final Approval of Proposed Standard N721

Internal Dosimetry Standards for Tritium

Authorized By: John W. Poston, N13 Chairman

Distributed By: MaryJo McCarrick, N13 Staff Assistant, on June 5, 1979

RETURN TO: Health Physics Society, 4720 Montgomery Lane, Bethesda, MD 20014

DUE DATE: August 6, 1979

SHALL THE N13 COMMITTEE RECOMMEND TO THE BOARD OF STANDARDS REVIEW THAT THE REVISED PROPOSED STANDARD N721 BE APPROVED AS AN AMERICAN NATIONAL STANDARD?

I Vote: (✓) Yes ( ) No* ( ) Abstain*

Name Walter S. Cool Signature Walter S. Cool
Print or Type
Organization Dr. John V. Nehemias John V. Nehemias
Represented U S Nuclear Regulatory Commission Date 8/3/79

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over):

↘ follow

COMMENTS ON THE MAY '79 REVISION OF N721

On page 15, in equations 4 and 6, we would have preferred to have the half life shown, either as a number or even $T_{\frac{1}{2}}$. This would have made it a bit easier for users who may choose to follow the excretion of the individual involved and to calculate the dose to the individual based on the observed half life. Further, it would be of some help to express the equations such that it is very clear which items are included in the exponential functions.

On page 20, lines 6 and 7, it would be helpful if the words "if any" could be added to read: "...All special dosimetry evaluations shall be dated and signed by the person making the evaluation and computerized records, if any, shall be traceable to the responsible person." The intent of the change being to avoid any implication that computerized records are required.

COMMITTEE CORRESPONDENCE

SOCIETY/COMMITTEE:

ANSI Committe N13

RECEIVED

AUG 10 1979

SUBJECT:
N721, "Internal Dosimetry Standards for Tritium"

ADDRESS CORRESPONDENCE TO:
Walter S. Cool
Occupational Health Standards Branch
Office of Standards Development
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

AGENDA ITEM:
FILE NO.:

DATE: AUG 8 1979

TO: Health Physics Society
ATTN: MaryJo McCarrick, N13 Staff Assistant
4720 Montgomery Lane
Bethesda, Md. 20014

Gentlemen:

Enclosed is our ballot on N721, "Internal Dosimetry Standards for Tritium". You will note that it is an affirmative ballot, with comments.

Some portions of the NRC staff feel that the Working Group was not responsive to some of our original concerns (comments enclosed with our letter of March 21, 1979), and continue to have reservations about the direct implementation of the N721 standard as an NRC Regulatory Guide. Such a guide will, presumably, draw from N721 and from the NRC interim "Guidelines for Bioassay Requirements for Tritium," a copy of which was transmitted with the letter of March 21, 1979.

Sincerely,

Walter S. Cool

Walter S. Cool
Member, N13

John V. Nehemias

Dr. John V. Nehemias
~~Alternate~~ Member

Enclosures:
As stated

RECEIVED

AUG 22 1979

LETTER BALLOT

ANSI COMMITTEE N13

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Authorized By: John W. Poston, N13 Chairman

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I Vote: ( ) Yes ( ) No* ( ) Abstain*

Name Gail D. Schmidt Signature Gail D. Schmidt
Print or Type

Organization Represented Bureau of Radiological Health/FDA Date Aug 17, 1979

SINCE I AM LATE WILL ONLY RESPOND WITH COMMENTS.

*If checked, explanatory remarks need be provided in the COMMENTS Section.

COMMENTS (below and over);

1. The efforts of the committee in summarizing and stating the response to comments is most appreciated. They deserve our thanks.

2. The response to comments 3, 7, 17, 24, 31, 33 and 34 is considered inadequate.

3. Sec 5.1 Did you mean to refer to a

committed dose equivalent of 0.3 rem?
I totally fail to understand how to use
Sec 9.2 as an appropriately lower limit
for implementation.

4. Table 1 I don't understand the significance
of the material below the footnotes. It is
certainly not clear as to how to handle
the various concentrations. Further on
p22 App A which is supposed to clarify,
the first sentence says to exclude gases
while the sentence after the summation
states to include gases. ??
The summation of Ai is rather self-evident
until examined as to what to include. It
would appear that the total quantity handled
per day is impt. as well as the max activity.
Surely handling 50 items of X Ci is
more significant than only one.

5. Sec 8.7 If the use of percentage is acceptable then it should be allowed regardless of whether the sample is stated or stipped.

6. Sec. 8.8 Did you mean that the individual must void completely at least one hour after last exposure at the sample collected subsequently It is not very well stated.

7. Sec 9.6 - 9.9 This material could stand editing for clarity. In 9.6 it appears that Eq 2 is in fact omitted dose equivalent (see Eq 7). Since Eq 3 is limited to $T \leq 7$ days in Eq. 5 also so limited. Is there sufficient difference between the chronic use Eq. 5 and Eq 6 (assumes exposure at midpoint) to treat as two separate cases.

8 App A p 23 The value of 0.5 is the same as Column 3 and thus it is not clear that it exceeds Table 1.

9. Comment & Response There is no Sec. 6.5

10. Comment 28 Response I/S only certain preservatives are appropriate then guidance should be provided.

SORRY ABOUT THE HAND WRITTEN COMMENTS

GD 8/17