NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Technical Report 32-1209

Terminal Sterilization Process Calculation for Spacecraft

A. R. Hoffman

J. A. Stern

JET PROPULSION LABORATORY

CALIFORNIA INSTITUTE OF TECHNOLOGY

PASADENA, CALIFORNIA

November 15, 1967

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Technical Report 32-1209

Terminal Sterilization Process Calculation for Spacecraft

A. R. Hoffman
J. A. Stern

Approved by:

W. S. Shipley, *Manager*
Environmental Requirements Section

JET PROPULSION LABORATORY
CALIFORNIA INSTITUTE OF TECHNOLOGY
PASADENA, CALIFORNIA

November 15, 1967

Contents

Tables

Figures

Abstract

To satisfy the planetary quarantine requirement, a dry heat thermal sterilization process may be applied to a planetary spacecraft prior to launch. Because of the complexity of the vehicle, it is important that the terminal process be the minimum necessary to assure that the desired sterility has been attained so as to maximize the reliability of both the spacecraft and the mission. Analytical studies have been performed for the purpose of identifying various facets of the process. A mathematical model was constructed. The model was based on a simple geometrical configuration and assumed a logarithmic survival of microorganisms. Various aspects that influence the thermal process parameters of time and temperature were studied. It was shown that transient lethality – that is, lethality during heat up and cool down – may significantly influence the time required at sterilization temperatures.

Terminal Sterilization Process Calculation for Spacecraft

I. Introduction

The terminal sterilization process that will be used on planetary flight hardware will be a function of many factors, including: the design; the thermal characteristics; the method, materials, and techniques used in the assembly; the microbial load distribution; the thermal resistance of the microorganisms; and the desired level of sterilization. Because of its possible deleterious effects on components of complex vehicles, it is important that the sterilization process be the *minimum* necessary to confidently assure that the desired level of sterility is attained, so that its effect on the reliability of the spacecraft and mission will be minimal.

When sterilization of lunar and planetary spacecraft was initially conceived in the late 1950s and early 1960s, the scientific community concerned with the sterilization problem turned to the techniques and procedures developed in the food processing and medical fields. The basic problem in the food industry – that of maximizing the destruction of microorganisms that cause food spoilage while minimizing the loss of the nutritive properties of the food – is analogous to the basic problem in spacecraft sterilization. For spacecraft, the problem is to maximize the destruction of microorganisms so that the desired level of sterility can be confidently assured and to minimize the loss of reliability caused by degradation of components resulting from extreme heat exposure. This suggests that analytic techniques, analogous to those in the food industry, could be used in the spacecraft sterilization. However, the analytic techniques, as well as the supporting experimental data from the food industry, were based on processes involving *moist* heat. Since moisture was another unknown parameter affecting spacecraft reliability and was difficult to control during a process, sterilization of spacecraft with dry heat processes was considered more desirable. Hence, the supporting experimental data for moist heat may generally be inapplicable to spacecraft, but the numeric analytic techniques form a basis for performing sterilization process calculations for spacecraft.

The requirements of the heat processing operation in the preservation of foods are (1) to be severe enough to destroy microorganisms present in the foods capable either of decomposing the foods or endangering the health of persons consuming the foods, or both, and (2) to be mild enough to preserve the nutritive properties of foods – many of which are heat labile. In other words, it is essential that the thermal processes be of the minimum intensity necessary to ensure the production of bacteriologically safe products. Before the introduction of numeric-analytic techniques, thermal processes for foods were determined almost entirely by trial and error.

The first analytic approach to the determination of a heat process was that developed by Bigelow, Bohart, Richardson, and Ball in 1920 (Ref. 1). Their method was a graphical integration of the lethal effects of the various time–temperature relationships that exist at the point of greatest temperature lag in a hermetically sealed container of food during heat processing. The General Method, as this technique came to be called, was based on the concept of thermal-death time (TDT), the length of time necessary to kill all of the organisms in a given suspension at a particular temperature. Ball (Refs. 2 and 3) developed a mathematical procedure for integration of the lethal effects of heat, based on the thermal-death time, that was simpler and more versatile than the method proposed by Bigelow et al.

Stumbo (Ref. 4) modified the General Method and Ball's mathematical procedure by introducing the concept of D values, which related the number of microorganisms present in a product to the severity of the sterilization process. The term D is defined as the decimal reduction time, or the time at temperature, required to destroy 90% of cells. It represents the slope of the survivor curve.

To transform these numeric analytic techniques for application to spacecraft process calculations and to provide insight into the effects of various facets of the terminal sterilization process calculation, a conceptual analytic model was developed.

II. Assumptions

Certain time–temperature and microbiological information is required before performing process calculations in the food industry (Ref. 5). Analogous information is required for process calculations on the conceptual spacecraft analytic model. It is necessary to have the following inputs: (1) a heating curve for the heating media, (2) a temperature profile that describes the thermal characteristics of the model – or point(s) – when exposed to the thermal environment of the terminal sterilization cycle, (3) the microbial loading on the model, (4) the probability of survival required to satisfy planetary quarantine constraints, (5) the thermal-death-time curve (or sterilization-time curve) for the organisms considered to be most heat-resistant.

The basic calculation assumes logarithmic survival of microorganisms that, although the validity of the function has been questioned by many (Refs. 6, 7, 8), is deemed sufficient for the purposes and scope of this study. All the microorganisms on the model are assumed to be heat-resistant spores with a D value of 3.5 h and a z value[1] of 25°C. It was also assumed that no lethal effects occurred below 100°C. The number of microorganisms initially present was assumed to be 10^5, and the required probability of survival on the model is 10^{-3}.

III. Model Configuration

For the purposes of this study, a simple geometric configuration of a spacecraft was assumed. The model representing a spacecraft is a 16-ft-long cylinder, with an 8-ft radius, constructed of homogeneous material and insulated at the ends (Fig. 1). This simple model was selected to facilitate making a thermal analysis. The dimensions are arbitrary, but they do approximate the dimensions of a large planetary spacecraft. It is assumed that the model could be divided into zones, or shells, of constant altitude. [Eleven positions r_1 to r_{11}, ranging from 0.05 to 8 ft, were selected (Fig. 1) for this study.] The criterion for establishing the zones of the model is the thermal behavior of particular shells. For the actual spacecraft, other factors – such as the functional attributes of subsystems and geometry of the configuration, in addition to the thermal properties – will undoubtedly influence the selection of the zones for the calculation of process parameters.

IV. Thermal Analysis

To determine the temperature profiles for each zone of the cylinder, a thermal analysis was performed, with the following assumptions:

(1) The heating curve for the heating media is linear, starting at 22°C (initial temperature) and arriving at the maximum processing temperature of 125°C in 9.4 h. Previous spacecraft data indicated that a heating rate of 10 to 15°C/h could be tolerated by spacecraft.

(2) The temperature profile for the most heat-resistant point of the model, shell r_{11}, was extrapolated from a heating curve in a study report

[1] z is numerically equal to the number-of-degree change in temperature required for a thermal-death curve to traverse one log cycle. It is the negative reciprocal of the slope of the thermal-death-time curve.

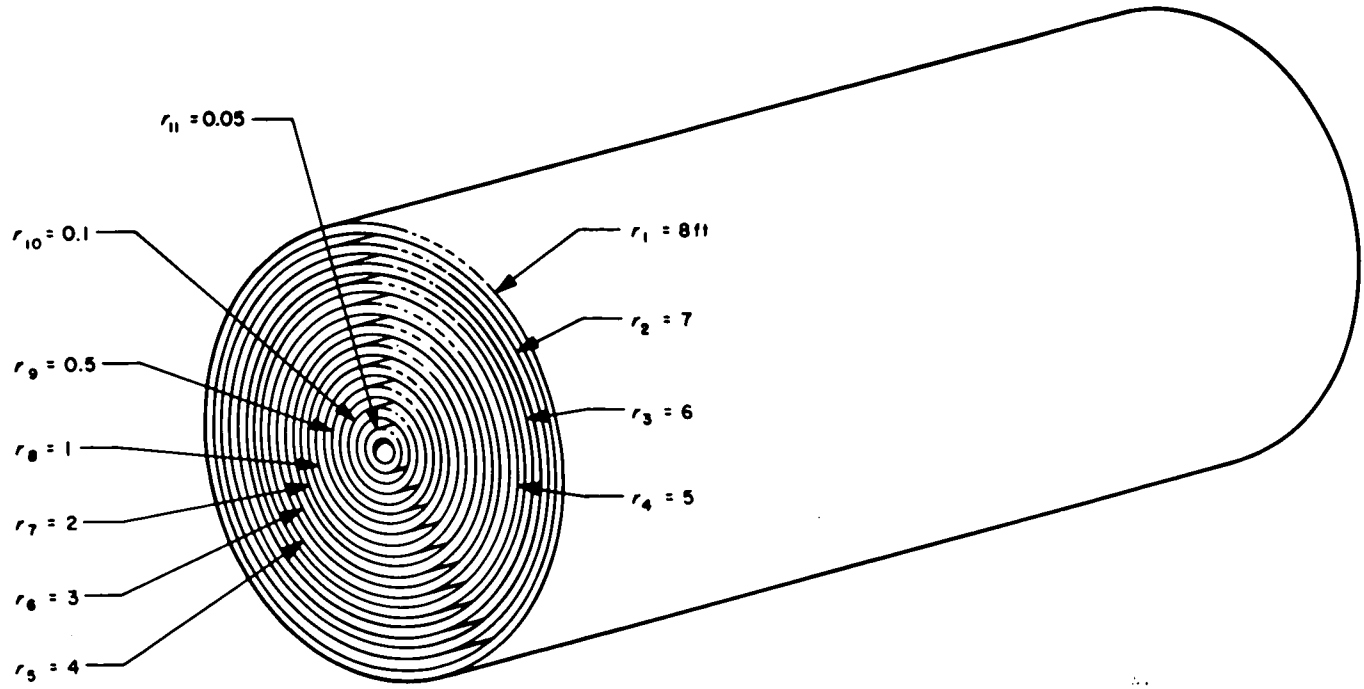

Fig. 1. Analytic sterilization model

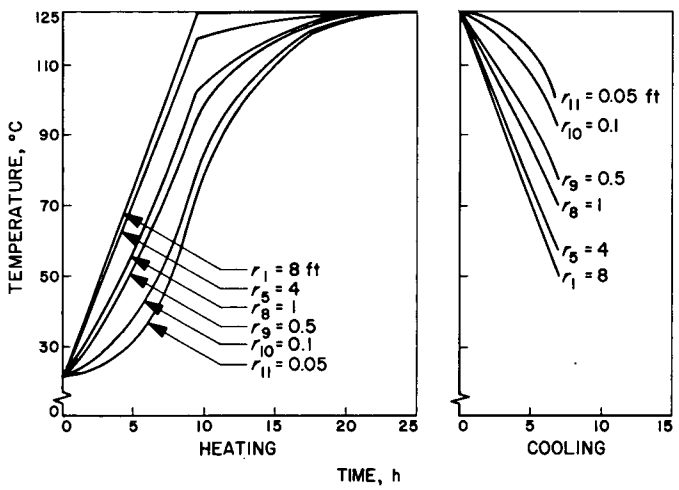

Fig. 2. Temperature profiles of cylinder shells

(Ref. 9) concerned with the heating and cooling of a titanium aeroshell. The curve shown in Fig. 2 differs from that in the referenced report because of the difference in media ramp-rates. The time to maximum-processing temperature for the study profile was 6 h; the time used in this analysis, for the reasons noted above, was 9.4 h.

(3) The surface temperature profile, i.e., the profile of the 8-ft shell, equals the heating media profile.

The other temperature profiles given on Fig. 2 are computed as shown below.

The heat flow in an infinite cylinder is given by

$$\frac{q_i}{l} = \frac{2\pi k (T_i - T_{i+1})}{\ln (r_{i+1}/r_i)} \qquad (1)$$

where

q_i = the heat flowrate for r_i shell

k = thermal conductivity

T_i = temperature at r_i shell

l = length of cylinder

Since the cylinder is homogeneous, the steady-state heat flow is a constant throughout the cylinder. It is assumed that, at a given instant (i.e., at discrete times), during the heating and cooling portions of the process, the heat flow is steady state. For an actual spacecraft, the transient thermal behavior will have to be adequately determined by combining the results of temperature-control model tests and a transient analysis. However, for the scope of this study, the simple thermal model developed appears sufficient.

Thus,

$$q_1 = q_2 = \cdots = q_{11}$$

Hence,

$$\frac{2\pi k (T_1 - T)}{\ln (r/r_1)} = \frac{2\pi k (T_1 - T_{11})}{\ln (r_{11}/r_1)}$$

Which simplifies to

$$\frac{T_1 - T}{T_1 - T_{11}} = \frac{\ln (r/r_1)}{\ln (r_{11}/r_1)}$$

And finally, rearrangement of terms gives

$$T = (T_{11} - T_1)\left[\frac{\ln (r/r_1)}{\ln (r_{11}/r_1)}\right] + T_1 \qquad (2)$$

where

T_{11} = Temperature at time t of innermost shell, r_{11}

T_1 = Temperature at time t of outer surface, r_1

r_1 = radius of shell r_1 = 8 ft

r_{11} = radius of shell r_{11} = 0.05 ft

V. Lethality Calculations

To determine the process parameters of time and temperature for the heating medium, it is necessary to account for the reductions in microbial population that occur during the transient phases of heating and cooling (described in Fig. 2) as well as at steady state.

To accomplish this, two factors are introduced: *lethality* (L) and *equivalent sterilizing time or process* (F_T).

Lethality is defined as a measure of the sterilizing process that, when equal to unity, is indicative that sterility has been achieved.

The equivalent sterilizing time or process is that time sufficient to achieve sterility, i.e., unit lethality, at a steady-state temperature, assuming instantaneous cooling and heating. Since a logarithmic microbial survival model was assumed for the study, and sterility was assumed to be obtained when the microbial population has been reduced to a level where the probability of survival is P_s, the equivalent sterilizing time (F_T) may be obtained by use of Eq. (3):

$$F_T = D_T \log \frac{N_0}{P_s} \qquad (3)$$

where

N_0 = initial number of microorganisms

D_T = time to reduce the specific microbial population by temperature T by 90%

The equation is sometimes expressed as

$$F_T = D_T [(\log N_0) - 1 - (\log P_s)] \qquad (3a)$$

to account for the initial reduction that is often encountered in the first few minutes of heating a microbial population. Equation (3a) is used in calculating all results presented in this paper except for those in the figure showing the relationship between D_T, F_T, and $\log (N_0/P_s)$.

The equivalent sterilizing time at any given temperature and for any ratio of N_0/P_s may be calculated by use of a thermal-death-time curve as shown in Fig. 3.

If a population of microorganisms (N_0) with given D_T characteristics is subjected to a process of F_T minutes at temperature T, sterility will be achieved, and the lethality of the process will be equal to 1. If the population had been exposed for only 1 min at temperature T, the resultant lethality would be equal to $1/F_T$. The term $1/F_T$ will be referred to as the lethal rate.

Lethality, therefore, is the product of the lethal rate and time, or

$$L = 1/F_T \times t_T \qquad (4)$$

The total lethality L_{TOT} of a sterilizing process for a particular point in the configuration may be obtained by calculating the lethality for each temperature during the cycle and summing all of the lethalities. Thus,

$$L_{TOT} = \sum_{i=1}^{m} 1/F_{T_i} \times t_{T_i} = 1 \qquad (5)$$

The total lethality of the process is also equal to the sum of the lethalities occurring during the heating and

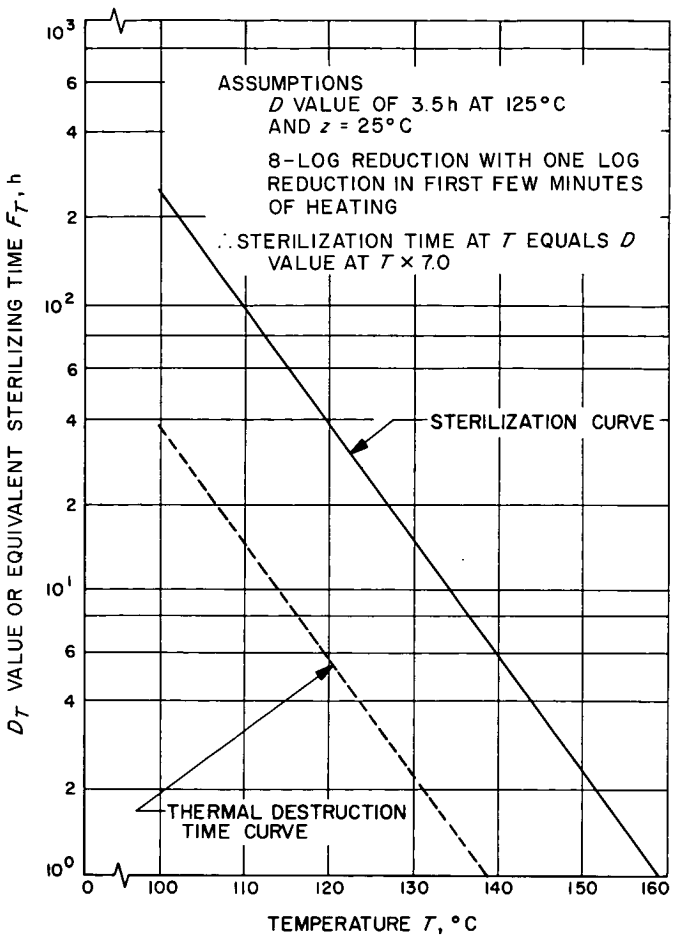

Fig. 3. Thermal destruction and equivalent-sterilization-time curves, most heat-resistant point

cooling phases of the cycle and the lethality occurring at the steady-state temperature, or

$$L_{TOT} = L_H + L_S + L_C \tag{6}$$

where

L_H = lethality during heating

L_S = lethality during steady state

L_C = lethality during cooling

The lethality occurring during heating (L_H) can be calculated by integrating all of the instantaneous lethalities occurring during the heating phase. This may be accomplished simply by making a graphical integration of a plot of lethal rate against time. In a similar manner, the lethality occurring during the cooling phase can be determined.

Then, since by definition the total lethality of the process must equal 1,

$$L_S = 1 - L_H - L_C \tag{7}$$

The total process time can then be determined by the addition of the times of the transient phases (for the particular point in the model under study) to the time calculated at steady-state temperature.

The total process time t_{TOT} can be represented by the following equation:

$$t_{TOT} = t_H + t_S + t_C \tag{8}$$

where

t_H = time required for heating

t_S = time required for steady state

t_C = time required for cooling to initial temperature

Since

$$L_S = 1/F_{T_S} \times t_S \tag{9}$$

where the subscript S is indicative of the steady-state condition; then,

$$t_S = L_S \times F_{T_S} \tag{10}$$

The t_S is the amount of time that the heating medium must remain at processing temperature after the appropriate monitoring point on the model has achieved the maximum. This concept of integration of lethalities can be demonstrated by applying the technique to determine the lethal effects of the transient phases of the thermal process.

Assuming all 10^5 spores are located at the most heat-resistant point of the model, i.e., shell r_{11}, then the equivalent sterilizing time F_T is determined by evaluating Eq. (3a),

$$F_T = D_T\,[(\log N_0) - 1 - (\log P_s)]$$

$$= 3.5\,[(\log 10^5) - 1 - (\log 10^{-3})]$$

$$= 3.5 \times 7 = 24.5\ \text{h}$$

The equivalent-sterilization-time curve and the thermal-death-time curve (Fig. 3) are both *isokill* curves; that is, all points on each of these lines are equivalent in their effectiveness to reduce microbial populations to a specific level. All points on the TDT curve reduce a population by 90%, while all the points on the sterilization-value curve produce an 8-log reduction in a population.

In other words, reference to the sterilization curve shows that 24.5 h at 125°C will produce the desired probability of sterilization (10^5 to 10^{-3}), which will also be produced by exposing the population to 97 h at 110°C or 37 h at 120°C.

If this 8-log reduction is assumed to be one F_T unit [i.e., sterility, or the time (t) in hours at temperature (T) necessary to reduce the population (N_0) to a level equivalent to P_s], the lethal rate, which is the reciprocal of F_T, at 125°C is 1/24.5 (or 0.041) units per hour. In other words, in 1 h at 125°C, the spores at the point under consideration receive about 1/25 of the heat necessary to bring about the 8-log reduction. At 110°C, the lethal rate is 1/97 (or 0.01) units per hour, and at 120°C, it is 1/37 (or 0.027) units per hour. It is assumed that there is no lethality below 100°C. The lethal rates at discrete times of the heating curve for zone r_{11} in Fig. 2 are tabulated in Table 1. The lethal rate as a function of heating and cooling times is shown for zone r_{11} in Fig. 4.

Table 1. Calculation of transient lethal rates, most heat-resistant point

Transient condition	Time, h	Temperature, °C	Sterilization time, h	Lethal rate, h^{-1}
Heating	13.1	100.0	245.0	1/245 = 0.00408
	15.0	110.0	97.0	1/97 = 0.0103
	17.5	119.0	42.1	1/42.1 = 0.0238
	20.0	122.5	30.6	1/30.6 = 0.0327
	25.0	124.9	24.5	1/24.5 = 0.0408
Cooling	1.0	123.8	27.1	1/27.1 = 0.0369
	2.0	122.5	30.6	1/30.6 = 0.0327
	3.5	120.0	37.0	1/37 = 0.0270
	5.0	115.0	61.0	1/61 = 0.0164
	6.0	108.8	107.0	1/107 = 0.0093
	7.0	100.0	245.0	1/245 = 0.00408

Assumptions: $D_{125°C}$ = 3.5 h, $F_{125°C}$ = 24.5 h, z = 25°C.

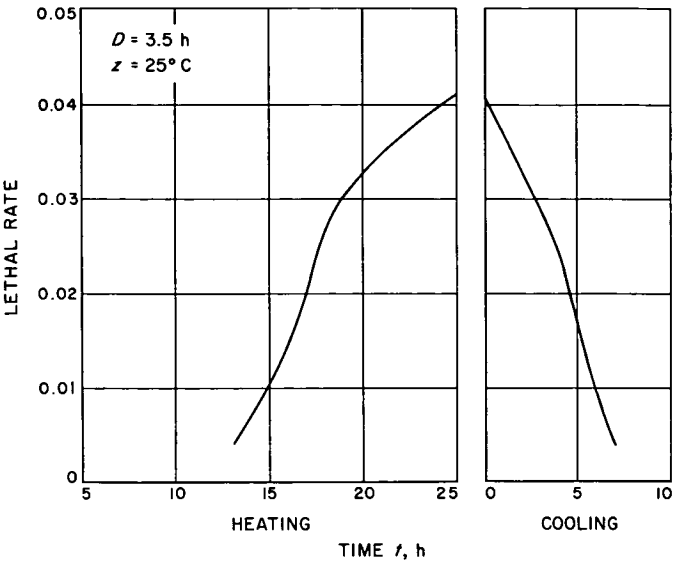

Fig. 4. Lethal-rate curves, most heat-resistant point

By graphically integrating the area under the lethal rate curves for shell r_{11} (Fig. 4), the lethality during heating and cooling are determined. Thus,

$$L_H = 0.290, \text{ and } L_C = 0.179$$

Hence, by Eq. (7)

$$L_S = 1 - L_H - L_C = 1 - 0.290 - 0.179 = 0.531$$

This computation indicates that nearly half the lethality will occur during the transient phases, and the other half must be accomplished while temperature is held at the maximum, 125°C.

The time at 125°C, then, is found by solving Eq. (10) for t_S,

$$t_S = L_S \times F_{T_S} = 0.531 \times 24.5 = 13.0 \text{ h}$$

Thus, the total process time, from Eq. (8), is

$$t_{TOT} = 25 + 13 + 18 = 56 \text{ h}$$

where, from Fig. 2,

$$t_H = 25 \text{ h}$$

$$t_C = 18 \text{ h}$$

If transient lethality (the lethality occurring during heating and cooling) were not considered, then, since $t_S = 24.5$,

$$t_{TOT} = 25 + 24.5 + 18 = 67.5 \text{ h}$$

Table 2. Effects of transient lethality on process times

Transient lethality	Total process time, h	Heat application time, h	Reduction in total process time, %	Reduction in heat application time, %
Considered	56.0	38.0	17.0	23.2
Not considered	67.5	49.5	—	—

The results of these calculations are given in Table 2. By use of the techniques presented here, a reduction of 23% in time of application of heat to the model to achieve sterility can be realized when all of the microorganisms are assumed to be at the most heat-resistant point.

Therefore, the lethal effects of the transient phases of a process should be considered during the establishment of spacecraft-sterilizing-process parameters. If transient lethality were not considered, overly conservative processes would result.

VI. Effect of Variation of Microbial Heat-Resistance Parameters

The effects of varying the heat-resistance parameters of D and z on process time have been studied.

In a paper presented recently at the COSPAR meeting in London, J. A. Stern and A. R. Hoffman (Ref. 10) discussed the relationship between D, F_T, and log (N_0/P_s). The curves of constant F_T value are shown in Fig. 5. At low D values, such as are encountered on spacecraft surfaces, it was shown that the F_T values are insensitive to changes in population numbers. Conversely, at high D values, such as are encountered in certain matings of surfaces and interiors, a small change in the term log (N_0/P_s) significantly affects the equivalent process time. As a result of these sensitivity studies, it was recommended that attention should be given to estimating the errors associated both with the assay techniques in estimating N_0 and with the establishment of D values to determine the controlling factors in the establishment of equivalent process times for use in calculating process parameters for spacecraft sterilization.

The relationship between D, F_T, and log (N_0/P_s) discussed above was concerned only with equivalent process times. This study has been extended to the calculation

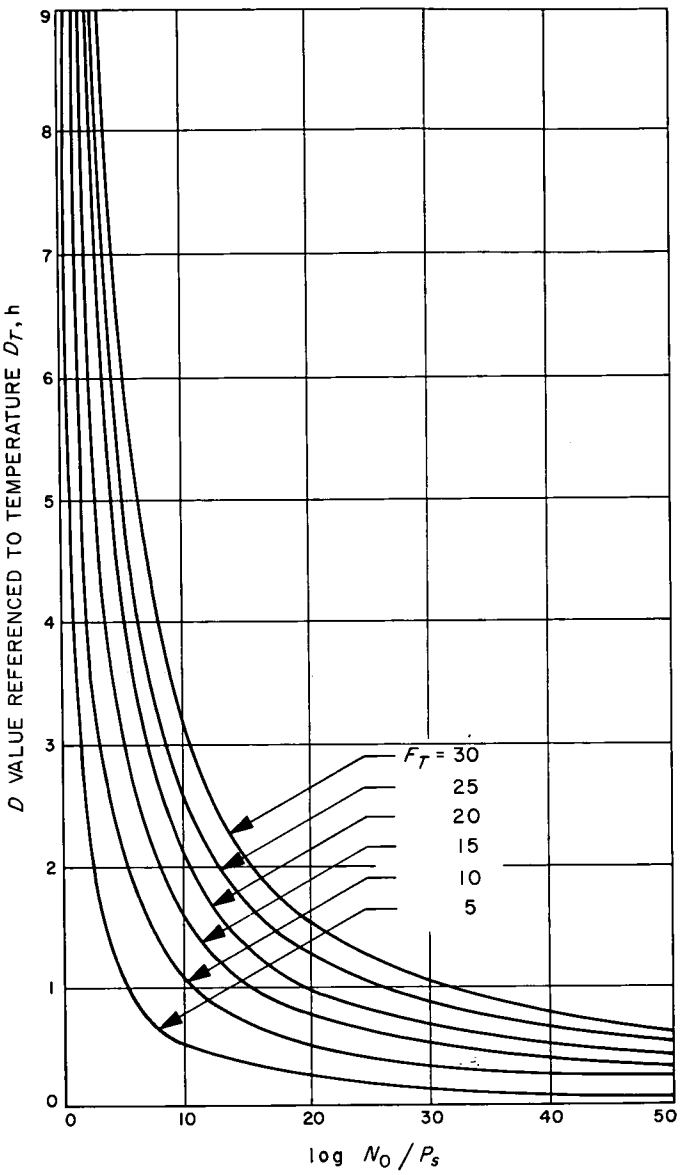

Fig. 5. Relationship between D_T, F_T and log (N_0/P_s)

of total process times by including the transient lethalities. For the study of the relationship between D and total process time, the thermal-death-time curves were varied but the slopes of the TDT curves (z) were held constant at 25°C, as shown in Fig. 6.

For the model that is considered here, the transient lethality calculation must account for three possibilities, from Eqs. (5), (6), and (8):

Case I: If $L_H + L_C < 1$, then $t_{TOT} > t_C + t_H$.

Case II: If $L_H + L_C = 1$, then $t_{TOT} = t_C + t_H = 43$ h.

Case III: If $L_H + L_C > 1$, then $t_{TOT} < t_C + t_H$.

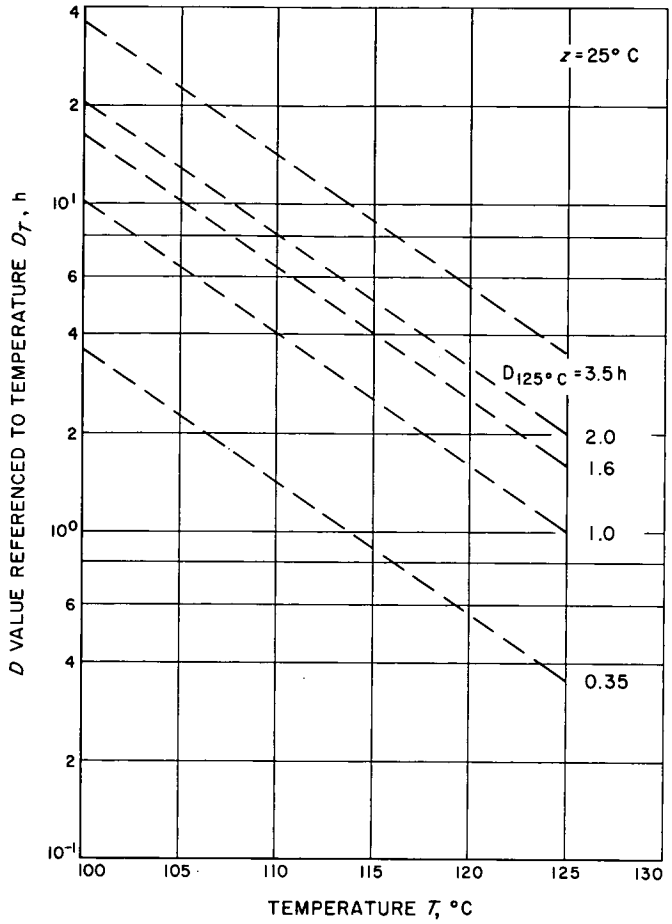

Fig. 6. Family of thermal destruction curves for constant z

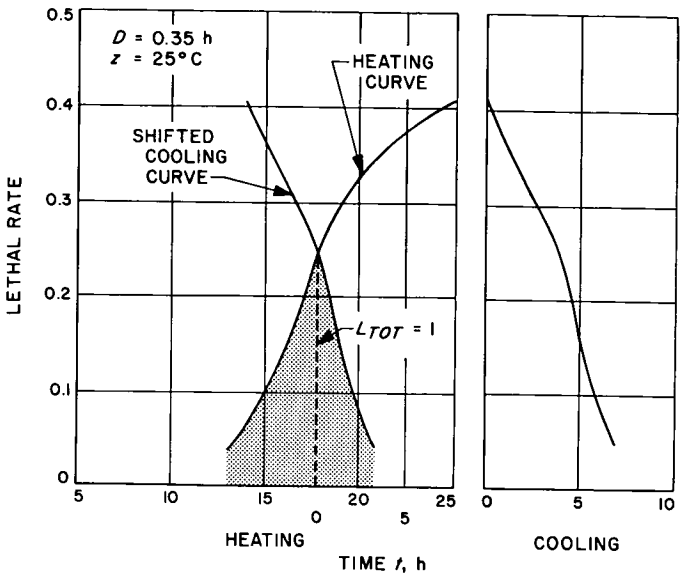

Fig. 7. Lethal-rate curves, Case III

Case I has been discussed earlier in the paper; the case requires additional time at temperature to achieve sterility, i.e., for $L_{TOT} = 1$.

Case II occurs when the heating and cooling lethalities exactly achieve sterility. Since z is constant and only D is to be varied, the implication is that there exists a unique thermal-death-time curve at which the transient lethality results in the required sterility. For the model considered here, the thermal-death-time curve of $z = 25°C$ passes through the point $D_{125°C} = 1.6$ h.

Case III occurs when the thermal-death-time curve ($z = 25°C$) passes through $D_{125°C}$ lower than 1.6 h. Then, the transient lethality is greater than that required to achieve sterility. This implies that sterility will be reached before the model's most heat-resistant point (zone r_{11}) is at 125°C. The heating and cooling lethal rate curves are overlaid on each other until the area underneath the curves is exactly equal to one. An example is shown in Fig. 7. The point of intersection of the heating and cooling curves determines the maximum lethal rate from which the maximum temperature can be determined. The time for heating t_H is the time on the heating curve to the point of intersection; and after the maximum temperature is determined, the cooling time can be read from the temperature profile. From Fig. 2,

$$t_H = 17.5 \text{ h}$$

$$t_C = 13.3 \text{ h}$$

and the maximum temperature reached at the most heat-resistant point in the model is 119.6°C.

Figure 8 presents the relationship between $D_{125°C}$ (when $z = 25°C$) and the total process time for the model. The curve is nonlinear for $D_{125°C}$ values less than 1.6 h, which corresponds to that portion of the curve where Case III occurs. However, for $D_{125°C}$ values above 1.6 h, corresponding to Case I, the curve becomes a straight line, indicating that a linear relationship exists at higher $D_{125°C}$ and total process time. This can also be shown mathematically (see Appendix). The sensitivity of total process time to changes in $D_{125°C}$ can be seen readily from the figure.

In our previous paper (Ref. 10), we indicated that the process parameters may also be affected by the microbial heat-resistance parameter z. As shown in Fig. 9, as the slope of the equivalent-sterilization-time curves decreases (and z, therefore, increases), the values of D_T at temperatures less than 125°C also decrease. Hence, if D_T is reduced, so must F_T; and $1/F_T$ will increase. Thus,

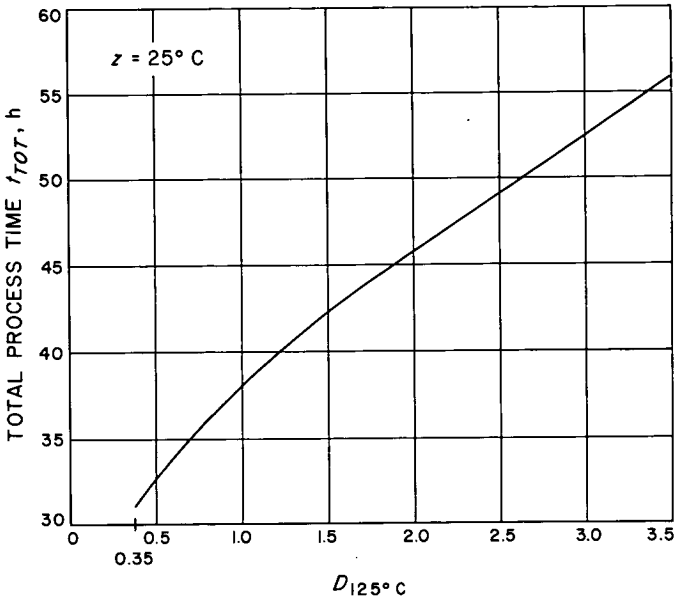

Fig. 8. Relationship between *D* values and model process time

it would be expected that greater lethality would result from the transient phases with a resultant shorter process time. As shown in Table 3, a fourfold increase in z value results in an 8% reduction in total process time for the model. The resultant process time is not greatly reduced, because of the assumption that all of the equivalent sterilization-time curves for the different z's pass through $F_{125°C}$ = 24.5 h ($D_{125°C}$ = 3.5 h). This causes the lethal-rate curves to converge as the model temperature approaches 125°C. As a result, when increased z values are considered, the difference in lethal rates affects the calculation at the lower temperatures when time is short; and comparatively small increases result in the lethalities calculated for the transient phases. Thus, the net effect is a relatively small reduction in process time.

As a result of these studies, it appears that model process times are extremely sensitive to D values and

Table 3. Effects of changes in z values on model process times

z value, °C	Total process time, h	Heat application time, h	Reduction in total process time, %	Reduction in heat application time, %
25	56.0	38.0	—	—
50	53.5	35.5	4.5	6.6
100	51.6	33.6	7.9	11.6

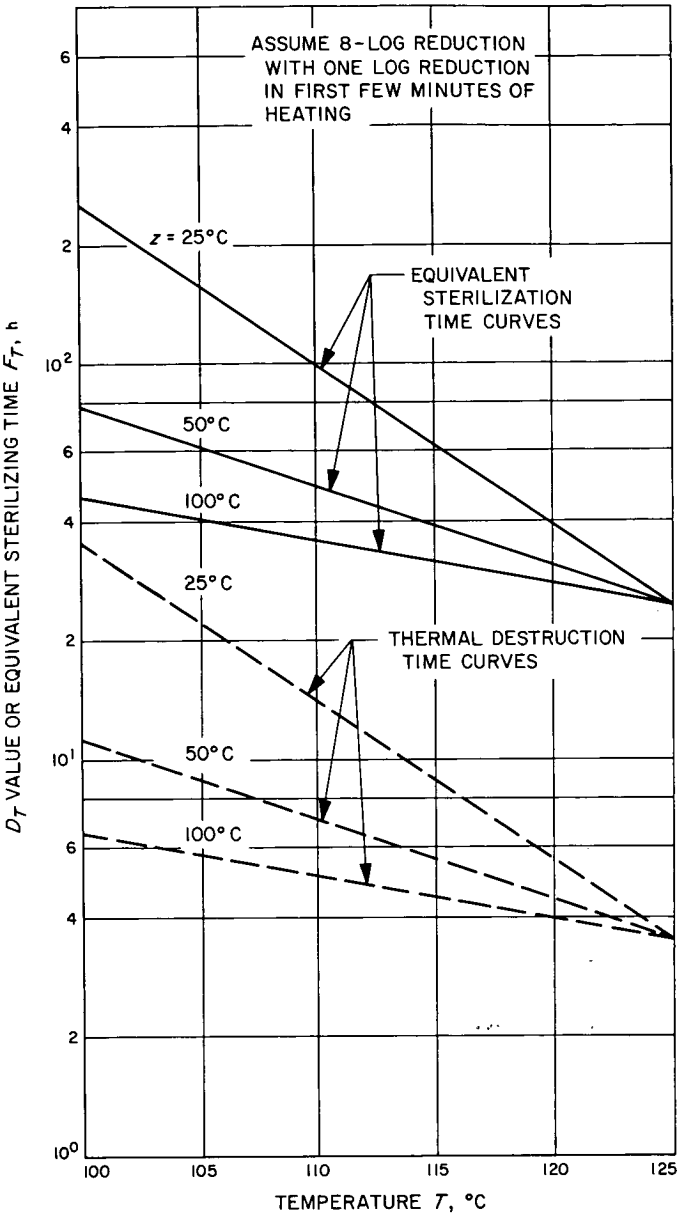

Fig. 9. Thermal destruction curve and sterilization-time curves of different z values

are only slightly affected by changes in z. Thus, efforts to more accurately determine D values, rather than z values, should be emphasized.

There are several other factors that will affect the determination of terminal sterilization process time, both for the model and the actual spacecraft, including the distribution and location of the population of microorganisms on the model or spacecraft and the thermal characteristics of the vehicle. These factors have been reported previously and will not be considered in detail

here. The conclusions from the studies indicate that the process time may be significantly affected by the population distribution, and therefore, a requirement exists for determination of the distribution and location of the microbial burden to calculate the minimum required process.

The thermal characteristics of either the spacecraft or its individual assemblies are also of importance in establishing the terminal-process parameters. If the model has high conductivity, the lethality during heat application phases is high and results in a short process time. Conversely, if the model has low conductivity, the model heats slowly and results in a long process time.

VII. Summary and Conclusions

In summary, then, it has been demonstrated that the analytic, numeric techniques long applied in the food industry for calculation of sterilization processes may be adapted to the calculation of spacecraft terminal sterilization process that uses dry heat.

Theoretical analysis has been accomplished by use of a simple, conceptual, analytic, geometric model. By use of this model, it has been shown that the inclusion of transient-phase lethalities will significantly affect the calculated sterilization process time and that neglect of these lethalities in the calculations will result in overly conservative processes.

In addition, it has been shown here that the terminal sterilization process calculations are sensitive to changes in D values and are relatively insensitive to changes in z values. Accordingly, it is recommended that emphasis be placed on accurate determination of D values rather than on z values.

Appendix

Mathematical Relationship Between $D_{125^{\circ}C}$ Values and Total Process Time

From Eq. (6), the total lethality of the sterilization process is equal to the sum of the lethalities occurring during the heating and cooling phases of the cycle and that at the steady-state temperature:

$$L_{TOT} = L_H + L_S + L_C = 1$$

Suppose each D value used in the above lethality equation is multiplied by a constant, $a \geq 1$. Or equivalently, the equivalent-sterilization-time curve is multiplied by the constant a. The new total lethality can be represented by

$$L^*_{TOT} = L^*_H + L^*_S + L^*_C$$

since

$$L^*_H = \sum \frac{1}{F^*_{T_i}} \times t^*_i = \sum \frac{t^*_i}{D^*_{T_i}\left[(\log N_0) - 1 - (\log P_s)\right]}$$

$$= \sum \frac{t_i}{aD_{T_i}\left[(\log N_0) - 1 - (\log P_s)\right]}$$

$$= \frac{1}{a} \sum \frac{t_i}{D_{T_i}\left[(\log N_0) - 1 - (\log P_s)\right]} = \frac{L_H}{a}$$

because $t^*_i = t_i$ for transient phases.

Similarly, it can be shown that

$$L^*_C = \frac{L_C}{a}$$

Thus, for sterility,

$$L^*_{TOT} = \frac{(L_H + L_C)}{a} + L^*_S = 1$$

and solving for L^*_S,

$$L^*_S = 1 - \frac{(L_H + L_C)}{a}$$

Note that $L^*_S \neq \frac{L_S}{a}$.

For total process time

$$t^*_{TOT} = t^*_H + t^*_C + t^*_S$$

but

$$t^*_H = t_H, \text{ and } t^*_C = t_C$$

and

$$t^*_S = F^*_{T_S} \times L^*_S = F^*_{T_S}\left[1 - \frac{(L_H + L_C)}{a}\right]$$

Since $F^*_{T_S} = aF_{T_S}$, then,

$$t^*_{TOT} = t_H + t_C + aF_{T_S}\left[1 - \frac{(L_H + L_C)}{a}\right]$$

$$= t_H + t_C + F_{T_S}[a - (L_H + L_C)]$$

which is linear.

If $a < 1$, then the arguments above are still valid as long as the thermal-death-time curves identified by aD_{T_S} are greater than the *unique* thermal-death-time curve at which the transient lethality results in the required sterility.

Nomenclature

a	arbitrary constant ≥ 1
D_T	D value referenced to a given temperature T
F_T	equivalent sterilizing time
k	thermal conductivity
l	length of cylinder
L	lethality: measure of sterilizing process that, when equal to unity, is indicative that sterility has been achieved
L_C	lethality occurring during cooling
L_H	lethality occurring during heating
L_S	lethality occurring during steady state
L_{TOT}	total lethality
N_0	initial number of microorganisms
P_s	probability of survival
q	heat flowrate
r_1 to r_{11}	radii of zones, or shells, of constant altitude in cylindrical model
t	time
t_C	time required for cooling
t_H	time required for heating
t_S	time required for steady state
t_{TOT}	total process time
T	temperature
T_i	temperature at r_i shell
TDT	thermal-death time
z	temperature degree change for thermal destruction curve to traverse one log cycle

References

1. Bigelow, W. D., Bohart, G. S., Richardson, A. C., and Ball, C. O., "Heat Penetration in Processing Canned Foods," *National Canners' Association Bulletin No. 16L*, Washington, D. C., 1920.
2. Ball, C. O., "Thermal Process Time For Canned Foods," *Bulletin National Research Council 7*, Part 1, No. 37, pp. 1–76, 1923.
3. Ball, C. O., "Mathematical Solution of Problems on Thermal Processing of Canned Food," *University of California Publication Public Health*, Vol. 1, pp. 15–245, 1928.
4. Stumbo, C. R., "Bacteriological Considerations Relating to Process Evaluation," *Food Technology*, Vol. 2, pp. 115–132, 1948.
5. Stumbo, C. R., *Thermobacteriology in Food Processing*, Academic Press, New York and London, 1965.
6. Rahn, O., "Injury and Death of Bacteria by Chemical Agents," Biodynamica Monograph No. 3, *Biodynamica*, Normandy, Missouri, 1945.
7. Reed, J. M., Bohrer, C. W., and Cameron, E. J., "Space Destruction Rate Studies on Organisms of Significance in the Processing of Canned Foods," *Food Research*, Vol. 16, pp. 383–408, 1951.
8. Reynolds, H., and Lichtenstein, H., "Evaluation of Heat Resistance Data for Bacterial Spores," *Bacteriological Reviews*, Vol. 16, pp. 126–135, 1952.
9. *A Study of Design Guidelines for Sterilization of Spacecraft Structures*, NASA CR 61105, General Electric Co., Space Technology Center, Philadelphia, Pa., April 1964.
10. Stern, J. A., and Hoffman, A. R., "Determination of Terminal Sterilization Process Parameters," presented at the Symposium on Sterilization Technique for Instruments and Materials as Applied to Space Research, London, England, July 18–22, 1967.