

Tab C
Memo to C. E. MacDonald
dated APR 13 1979

Recommendations on Concerns
Expressed by the Project Manager

The following discussion attempts to identify, interpret and make recommendations towards resolving those specific concerns* expressed by the Project Manager.**

This Tab may be supplemented as additional concerns are discovered.

All quotations shown herein are taken from Reference (1), Tab F, herein. Parenthetical comments are added for clarity.

* The subject concerns are shown in Reference (1), Tab F. The terms "Enclosure (1)" and "Enclosure (2)", herein, refer to the enclosures of that reference.

** Mr. C. E. MacDonald is understood to have withdrawn his previous delegation of authority as Project Manager to W. Lake by acting as shown in Reference (2), Tab F. Mr. MacDonald, therefore, is the Project Manager referred to herein.

- C.1 "Enclosure 1 is considered incomplete ... (it) should include all of your recommendations for additional information to be transmitted to the applicant including identification of problem areas, deficiencies in the application, etc.."

Recommendations:

- a) The accomplishment of this objective is self-evident in the text of Enclosures (1) and (2) with the exception of "etc." which defies assessment. The staff shall report recommendations relevant to "etc." pending clarification of this expectation in a supplement to this report.
- b) Enclosures (1) and (2), considered separately, may be construed as not complying with either the letter or spirit, or both, of this objective. However, it should be noted that these Enclosures were twice submitted (and accepted and acted upon) jointly.^{2,4*} The second submittal expressly requested they be considered jointly. So considered, they are especially clear in demonstrating compliance with this objective. Tabs A and B are submitted herein for the third time in a continuing attempt to identify the project Manager's specific concerns on a trial and error basis.
- c) Versions B and C (Tabs A and B herein) show the comments together with the concerns upon which they are based in an attempt to clarify those problem areas or deficiencies considered most significant to safety by the staff. It is recommended that either be substituted in issuance of comments to the applicant.

- C.2 "Enclosure 1 is considered ... not adequate ... as a staff document ...", and

"Enclosure 2 is not considered acceptable as a staff document."

Recommendation:

- a) In comparison to other (adequate) staff documents⁵⁻¹⁸, Enclosure (1) appears to be eminently qualified as such.** In the continuing absence of a description or commitment to a workable and mutually understandable definition of either "adequacy", "acceptability" or "staff document", the basis of concern here is obscure.^{17,2}

* Numbers in superscript correspond to References listed in Tab H, herein.

** For example, in that the applicant's submittal has been "accepted" to date, it may be used as a standard of comparison.

- b) Enclosures (1) and (2) were not intended, nor were they prepared and submitted, exclusively as "staff documents". Both are intended for public issuance together ⁴ and may be so distributed together with relevant "staff documents," e.g., this memo, at the appropriate step in the licensing process and consistent with standing policies and practices.
- c) Recommendations C.1.b, C.1.c, C.5.a and C.22.c are also applicable here.
- d) In that the staff is expected to be specific with respect to the basis for identifiable "problem areas" or "deficiencies", it would seem consistent and reasonable to expect officials to set an example. This is not only reasonable but a requirement under standing NRC regulations, e.g. NRCM 4151.
- e) It is recommended that this concern be assumed unfounded pending discovery of a substantive basis in fact. This has been the Branch practice, in converse, for a minimum of two years.
- f) Most recent FCTR license review practice is to document the results of staff reviews of applicant submittals in a disparate manner as shown in the Table 1. This memo is submitted in suggestion that understandable and consistent guidelines be formulated and adopted as to enhance the expectation that the following objectives can be successfully achieved.

Objectives of the Improvements.*

Adoption of the suggestions proposed in the following discussion are expected to manifestly improve the licensing review process of the FCTR Branch by:

- (1) enhancing the expectation that applicant submittals will successfully resolve staff concerns in as timely a manner as possible.
- (2) significantly reduce the inhibition of the free expression of staff concerns.
- (3) enhance the expectation that licensing decisions will be based upon as scientifically sound and objective basis as is practically achievable.
- (4) establishing a more understandable and consistent basis of comparison for work products.

* See C.3.b for "Present License Review Practice" and C.3.C for "Problems".

- g) Presumably, to be adequate, a staff document should be complete (see C.1 above). It is suggested, in that context, that concern C.1 is best first resolved by the Project Manager's description of those specific aspects considered incomplete or missing.

Table 1

Present FCTR Transportation Package Review Documentation Practices,
12/29/78 to 1/30/79

<u>Staff documents:</u>	<u>Ref.*</u>
Document recommended Comments only	6
Document the Review Summary only	16
Document review basis for Comments and Summary basis for those Comments separately	5,12,14,17
A single document representing a combined form of Comments and Summary with an explicit identification of the staff concerns	9,10,11,13
<u>Issuances to applicants:</u>	
Issue a form of the staff comments recommended by the staff only, i.e., no identification of the staff concerns	7,8,15
Issue a form of the Comments recommended by the staff explicitly accounting for the basic concerns (proposed)	(none)

*
As shown in Tab H herein.

- C.3 "Enclosure 1 is considered ... not adequate for transmittal to the applicant ..."

Recommendations:

- a) Recommendations C.1.b, C.2.a, C.2.b, C.2.d, C.2.e, C.2.f, C.22.a and C.22.c are also applicable here.

- b) Present License Review Practice.

Most recent license review practice in the FCTR Branch 5¹⁸ represents a significant improvement over precedent practices in that Summaries* are now permitted to be expressed to the record relatively free of inhibition. The results of a staff review of each licensing case work product can be characterized as composed of three separable** elements:

- (1) Comments recommended for issuance compiled by the individual staff reviewer, when applicable (a "staff document" compiled in those cases where Comments are necessary)
- (2) Summary of the license review compiled by the individual staff reviewer (an optional "staff document" showing the basis for the Comments, above),** and
- (3) Comments issued officially to both the applicant and the public record requiring a response by the applicant (a "public document")***

- c) Problems Encountered and Observed with the Present Practice

- (1) The "Comments..." can be required to be concise to the exclusion of any discussion or mention of the staff concerns upon which they are based. This inhibits mutual understanding, on the part of the applicant, of what is expected and contributes to the non-resolution of staff concerns at the earliest date practicable.

* Examples of Summaries are addressed in C.2.f as "Objectives of the Improvements", Table 1, C.2 and C.17.C herein.

** Elements 1 and 2 are not always separable or separate in fact, as indicated in Table 1, C.2.

*** Those license decisions not requiring such comments are beyond the scope of this memo.

- (2) Applicants, at their discretion, often substitute obscure and unsatisfactory information for that requested, i.e., the information submitted is not relevant or applicable to the basic staff concern. In such cases, the information submitted is not useful in a practical sense in resolving the basic concerns otherwise addressed to the internal record system as "staff documents."
 - (3) Committing the staff, in advance, to acceptance of a design based exclusively upon the scope (not content) of the additional information submitted delimits subsequent staff review to a purely auditory role.
- d) Towards suggesting specific alternatives, the staff offers the following statements of objectives and definitions understood to be applicable to present practices together with proposed alternatives.

Objective of Comments Recommended by the Staff:

- (1) The Comments should identify specific information required. If the applicant satisfactorily provides the information requested, the applicant will have demonstrated the adequacy of the design. (present practice)
 - (2) The same as (a), above, except that the staff should be free to review and assess the new information submitted consistent with the procedure used in the initial review rather than limiting itself to an auditory role. (proposed)
- e) Comments issued to applicants: (proposed)
- (1) The Comments may, at the discretion of the accountable reviewer, expressly account for the staff concern(s) upon which it based. (the present practice varies considerably; see Table 1, C.2.)
 - (2) The Comments should account for the staff concern(s) in each case towards enhancing the expectation of successful resolution of those concerns at the earliest point in time, i.e. response to initial comments.

It seems logical to suggest that the concerns apparent in C.2, herein, be resolved prior to addressing this and following concerns expressed by the Project Manager.

- C.4 "Enclosure 1 ... (should represent) the additional information required in the structural area."

Recommendation:

- a) The accomplishment of this objective is self-evident and implicit in the text of Enclosures (1) and (2) with the following possible exceptions:
- (1) Complimentary and supplementary information has been requested internally in support of staff review of some safety relevant features of the package. This is consistent with past practice. What is requested of the applicant is information either not available from other sources or unique to the package apparently in the sole possession of the applicant.
 - (2) In that this objective may be interpreted to apply to all information supportive of an independent staff assessment of some safety significant features of the cask, it is introduced here for the first time. The staff may supplement Enclosure (1) significantly if this is, in truth, what is expected.
 - (3) Enclosure (1) was not understood to be comprehensive and final with respect to additional information requested not only because of (1) and (2), above, but also in that information requested:
 - (a) may not confirm the applicant's positions as claimed or expected and thus not resolve the need for confirmatory information, or
 - (b) may prove irrelevant or otherwise not acceptable thus not resolving the need for complete information.
- b) Recommendations C.1.b, C.1.c, C.2.e and C.3.C are also applicable here.

- C.5 "(The comments transmitted to the applicant) should pass the test - if the applicant satisfactorily provides the information requested, the applicant will have demonstrated the adequacy of the design."

Recommendations:

- a) This aspect is discussed in C.3.b, C.3.c, C.3.e, C.17.c and C.23.

b) Recommendations C.1.b, C.1.c and C.4.a are also applicable here.

C.6 "(The Summary of Initial Structural Review of the ORNL Tungsten-Shielded Cask) should place emphasis on the structural review."

Recommendations:

a) Self-evident from the title and express scope of Enclosure (2). Those comments shown which are interpreted as beyond the scope of a "structural" review remain to be identified. The staff will then have a basis upon which to more fully respond to this apparent concern.¹⁷²

C.7 "The objective is confirming acceptability of and identifying problems with the package design in meeting the various general/specific package requirements and the determination of the effect on the package of various environmental conditions as specified in the regulatory standards."

Recommendations:

a) The accomplishment of this objective is self-evident from the text of Enclosure (2) with the following exceptions:

(1) Where acceptability cannot be confirmed the unresolved concern is described. The determination that a problem exists is expressly described as contingent upon continuing staff study to be reported in supplement.

To reiterate, for clarification, the assumption is that where a basis for demonstrating acceptable compliance with requirements is not submitted nor can the staff show definitely that a problem exists within existent schedule and resource constraints, the staff as an alternative, should not be inhibited in studying and reporting on given features at their discretion. In such a case the feature would not clearly qualify either as something whose acceptability could be confirmed or as an identifiable problem.

b) The identification of problems cannot be considered final in that case where safety significant information remains to be discovered, reviewed, or assessed.

To reiterate for clarification, where safety significant information:

(1) is not submitted, it remains to be discovered; review, assessment and problem identification remains pending in the interim.

- (2) is submitted but cannot be reviewed, assessment and problem identification remains pending in the interim.
- (3) is submitted and reviewed but cannot be assessed, problem identification remains pending in the interim.
- c) Recommendations C.1.b, C.1.c, C.4.a, C.8.a, C.9.a and C.11.a are also applicable here.
- d) Heretofore it has been Branch practice to expect the applicant to determine the effects of various environmental conditions as specified in the regulatory standards. It is recommended that, if the staff is to be expected to subsidize applications by completing such demonstrations, such an expectation should be expressed and accounted for in any schedule or resource allocation imposed. As a minimum, preacceptance reviews should be performed and committed to by the staff.

C.8 "The (review) should refer to the (regulatory) standards ..."

Recommendations:

- a) Please refer, for example, to page 3 of Enclosure (2), i.e., "The staff ... concludes that the cask is in compliance with (the structural standard) requirements (of 10 CFR Part 71.32).
 - b) No Regulatory Guides (if that's what's intended here) are applicable to this cask other than Regulatory Guide 7.8*, which is used as a basis in part as proposed.
 - c) Recommendations C.1.b and C.1.c are also applicable here.
- C.9 "(A structural review) should refer to ... facts bearing on the demonstration ..."

Recommendations:

- a) The accomplishment of this objective is self-evident from the text of Enclosure (2) with the following exceptions:
 - (1) no reference to facts which remain to be discovered is intended or implied. The comments recommended request the

* This Regulatory Guide has only been issued for comment to date and its status herein is therefore ambiguous.

submittal (discovery) of some facts bearing on the demonstration. NRC-Internal requests for information are expected to discover additional facts.*

(2) reference is made to continuing staff study of certain aspects of the capability of the cask to comply with the regulatory requirements. Until the results of these studies are available or an acceptable assessment is received from the applicant, these facts shall also be unavailable for reference.

b) Recommendations C.1.c, C.2.e, C.11.a and C.12.a are also applicable here.

C.10 "(A structural review) should refer to ... assumptions ..."

Recommendations"

a) The accomplishment of this objective is self-evident from the text of Enclosure (2) with the following exceptions:

(1) No reference to assumptions which remain to be discovered is intended or implied. However such discovery is not considered predictable.

(2) Implicit assumptions which are only suspected may be referenced in staff supplementary reports pending confirmation of that suspicion, i.e., findings shall be based on fact, not suspicion. In the absence of fact only suspicion remains and this is an inadequate basis for licensing action. The availability of facts is dependent upon support services at best only marginally effective to date.

b) In a sense, the expressions of differing view discussed in C.16 and Tab E, herein, could be considered assumptions. They remain to be resolved as such.

C.11 "(A structural review) should refer to the ... consideration of the facts ..."

Recommendations:

a) The accomplishment of this objective is self-evident from the text of Enclosure (2) with the following exceptions:

*
Some of which remain outstanding since March, 1977.

- (1) No reference to relevant facts withheld by the applicant is intended or implied. Such reference remains pending the submittal of such facts available only from the applicant and unique to the subject package.
 - (2) No reference to relevant facts cited or otherwise referred to which, due to unavailability, remain to be reviewed for acceptability is intended or implied. Such facts may be reported on in a supplement to the subject report pending such a review.
- b) Recommendations C.1.c, C.9.a and C.12.a are also applicable here.

C.12 "(A structural review) should refer to the ... conclusions ..."

Recommendations:

- a) The accomplishment of this objective is self-evident from the text of Enclosure (2) with the following exceptions:
- (1) No staff conclusions are drawn with respect to open items specifically identified as such in the text and comments, except in the implied sense that the conclusion is not to conclude at present.

To reiterate for clarity, some conclusions remain pending submittal or discovery of acceptable fact upon which to base conclusions. In the absence of such a factual basis, forced conclusions are likely to be inobjective and not complimentary to NRC's mission. In that such forced conclusions appear to be encouraged and acceptable in practice,* they could be expressed in a supplement to Enclosure (2). The staff shall await your express expectations in this respect.¹⁷²

- (2) Conclusions based upon fact are herein distinguished from conclusions based upon judgment. The latter type of conclusion, also shown in the text of Enclosure (2), infer that a complete factual basis is either unobtainable or unnecessary. It is noteworthy that the exercise of good judgment does not appear to be expected*. (see C.21, herein)

* FCTR-unique practice; disparate with both Agency and individual professional practice.

C.13 "(A structural review) should refer to the ... recommendations."

Recommendations

- a) The accomplishment of this objective is self-evident in the text of Enclosures (1) and (2)* with the following exceptions:
 - (1) Pending discovery of a complete and reasonably achievable factual basis for some of the engineered safety features of the package, recommendations are withheld. The reason, which should be superficially obvious, is that no basis exists for specifying a recommendation in a final, defensible form. Supplementary and consistent recommendations will be made pending compilation of a reasonably complete and achievable factual basis for license decision-making. Progress towards this goal, interrupted since December, 1978, can proceed pending straightforward description concerns.¹⁷²
- b) No Branch "recommendations" have yet been discovered or committed to with respect to any issue or aspect addressed herein. The staff recommends that such "recommendations" be expressed to the record.
- c) The staff notes that historic attempts to make recommendations directly to applicants have always been discouraged. Should this policy change, the staff should be informed and given guidelines.
- d) Recommendation C.21 is also applicable herein.

C.14 "(The Comments transmitted to the applicant) should be presented in a clear, specific, and concise manner."

and

"The information should be presented in a clear and concise manner which can be related to the additional information to be requested from the applicant (Enclosure 1)."

Recommendations"

- a) The accomplishment of this objective is self-evident in the text of Enclosures (1) and (2). Tabs A and B, herein, are submitted as a response to your request for alternatives and may be substituted at your discretion.

*
These submittals, as well as Tabs A and B herein, can also be considered "recommendations".

- b) The continued reluctance to define or express expectations with respect to the implication that submittals are either less than clear, less than specific or less than concise precludes positive action towards resolving this apparent concern.¹⁷²
- c) Recommendations C.1.b, C.1.c, C.15.a and C.15.b. are also applicable herein.

C.15 "Where references are used, they must be clear and specific as to what part of the reference is used and how it applies to the specific design under review."

Recommendations:

- a) The intent of the reviewer was to address his discussion and comments to an audience possessed of a minimum level of technical expertise to preclude the necessity for lay interpretations of the references. Both Enclosures (1) and (2), as shown, or Tabs A or B, herein, show in concise terms all that is necessary to such readers. Tab D is provided in supplement to these submittals as an aid to those readers not so familiar with the technical disciplines involved.
- b) This expectation, introduced here for the first time, is unique to this submittal. It is suggested that such concerns are best resolved in a timely manner independent of an inhibiting license review schedule.
- c) Recommendation C.1.b is also applicable here.

C.16 "If there are differing views on the matter, these should be addressed with the alternatives considered and with your recommendation as to the best alternative."

Recommendations:

- a) A differing view implies that at least two views have been expressed. So far only the originator's observations of various interpretations of the regulations have been reported in the form of a request for official confirmation of those interpretations and that request remains pending. In the apparent absence of such a confirmation or any other commitment to an official position relevant to those topics, no basis for a "difference" exists.

- b) Alternatively, there have been several official issuances to the record describing the originator's request as a differing view or expression of safety concerns. In view of the continued lethargy in responding to that request, these issuances imply commitment by superior officials to the interpretations as described. Assuming, then, that these interpretations have been so (officially) committed to, the originator concurs with the characterization of that memo dated November 4, 1977, as an expression of differing view.
- c) This additional assignment appears to require immediate resolution of concerns held in abeyance now for one and one-half years. Your introduction of that lethargic schedule into this licensing review is not this reviewer's responsibility, and is most untimely. The most serious implication is to appear to impose significant burdens upon the work performance of only those staff originating such views as a punitive action. The staff considers it reasonable to expect, and so requests the allocation of additional resources and work schedule appropriate to the professional treatment of the complex and unique issues involved in this license. Tab E, herein, was developed and is submitted on the basis that this is acceptable.
- d) Recommendations C.10.b and C.15.b are also applicable here.

C.17 "Enclosure 2 should pass the test - does the written summary represent an objective technical review which is clear, concise, and provides an assessment of the package design against the regulatory standards."

Recommendations:

- a) The accomplishment of this objective is self-evident from the text of Enclosure (2). Possible exceptions exist depending upon alternate interpretations of the term "regulatory standards"* It is assumed Title 10, Part 71, is referred to in the interim consistent with Branch practice.
- b) Recommendations C.1.b, C.1.c, C.13, C.14, C.15 and C.22.a are also applicable here.
- c) Summaries of reviews:
 - (1) Summaries may be documented at the discretion of the staff either together with or separate from the Comments, or not at all, and, if documented, shall be considered "staff documents" not available to either the applicant or the public. (present practice)

* Introduced in Ref (1).

- (2) Whether or not Summaries are documented, the staff concerns which constitute the basis for the Comments should always be shown in the issuance of those Comments. When documented, such Summaries should be made available to both the applicant and the public, i.e., copies sent to the PDR*. The decision to document such Summaries should still be left to the discretion of the individual reviewer since not all license cases will involve substantive staff concerns. The additional effort to document such Summaries is justified in those cases involving staff concerns which are not straightforward and thus requiring clarification to the record. Where Summaries are so justified, these additional efforts should be supported by official resources not usually accounted for in initial task assignment time or schedule allocations. (proposed)

C.18 "Deficiencies ... should be addressed ..."

Recommendations:

- a) The accomplishment of this objective is self-evident from the text of Enclosure (1) and (2).
- b) Recommendations C.1, C.2.e and C.22.a are also applicable here.

C.19 "... alternatives should be addressed ..."

Recommendations:

- a) The accomplishment of this objective is self-evident from the text of Enclosure (2) with the following exceptions:
 - (1) The identification or discussion of alternatives is precluded, in some cases, pending discovery of the supplementary facts necessary to clarify, and constitute a factual basis for, their description.
 - (2) Possible license conditions are considered an alternative and are shown in the text of Enclosure (2). They are shown in a more straightforward format in Tab B herein.
- b) Recommendations C.2.a, C.13.a, C.13.c and C.15.b are also applicable here.

* NRC Headquarters Public Document Room, H-Street.

C.20 "... the need for additional information to be requested from the applicant should be supported."*

Recommendations:

- a) The accomplishment of this objective should be accepted as self-evident from the text of Enclosure (2).
- b) Recommendations C.1.b, C.1.c, C.2.e and C.21 are also applicable here.
- c) Most information requested by the staff has been cited specifically by the applicant as a basis, in part, for demonstrating compliance with regulatory requirements of Title 10, Part 71. It is recommended that NRC adopt the position that, in so doing, the applicant has made that information a material part of the basis for a license decision. Consistent with that position, the information requested is that otherwise unavailable to the staff.

C.21 A structural review should involve the exercise of more mature technical judgement. (This reviewer's concern supplementary to Reference (1)).

Recommendations:

- a) This consideration seems to have been omitted from the statement of objectives and is included herein in suggestion that it be accounted for as a necessary attribute of the review.
- b) The accomplishment of this objective is evident in the text of Enclosures (1) and (2) with the following possible qualifications:
 - (1) Although a complete factual basis is considered reasonably achievable, experience teaches that responsible and effective decision-making can be accomplished based upon less than an ideally complete factual basis. The necessity for such decision-making is not yet established, however, in the absence of a serious effort to develop as complete a factual basis as reasonably achievable. The staff has recommended a continuing effort to collect such a basis, e.g., Enclosure (1).

* a requirement introduced in Ref. (1), Tab F

It is observed, understood and accepted that administrators may preclude the discovery of such a basis by the untimely imposition of procedural requirements.¹ In such a case, and by default and as a practical matter, the basis for license decision-making becomes increasingly dependent upon the application of such judgement, i.e., the introduction of non-facts into the decision basis. The unavoidable consequence is to preclude the discovery and account of materially relevant and available facts. In that sense, untimely and inhibitive administrative constraints applied to the review process are self-contradictory.

- (2) It is the staff's intent and practice to apply more mature technical judgement where appropriate. It is not considered a substitute for scientific fact when such fact can be accounted for compatible with administrative constraints on the review. The subject review has not yet been permitted to progress sufficient to discover or develop missing facts. Should that condition persist, then the exercise of the alternative will become necessary, i.e. a full account of all factual elements of the basis for license decision will be inhibited by the imposition of administrative constraints.

C.22 "The results of the initial structural review should be presented in a form which may more readily be used as completed staff work."

Recommendations:

- a) The accomplishment of this objective is self-evident from the text of Enclosures (1) and (2), especially:
- (1) considering the fact that the past Project Manager did so accept and act upon the submittal until (apparently and mysteriously) overruled by the present Project Manager.
 - (2) considered in comparison to the staff work of others, and
 - (3) considering that staff work of near exactly the same kind has been accepted in the interim.^{5 18}
- b) Recommendations C.1, C.2.a, C.2.d, C.2.e and C.23 are also applicable here.

- c) The completion of this staff work remains pending discovery of specific concerns. This memo may be supplemented as those concerns crystallize.¹⁷²

C.23 "Proposed License Review Practice"

a) Alternative:

Submit both the "Comments..." and the "Summary..." to the applicant.

This would identify to the applicant what the basic concern(s) of the staff is (are) and enhance the expectation of success in resolving those concerns in a timely manner.* In any case, the "Summary..." should be considered a part of the public record in compliance with the Atomic Energy Act of 1954, i.e., not withheld from that record.

The staff should be permitted to prepare a second "Summary..." and, consistent with the initial review objectives, a second "Comments..." based upon the cumulative record of submittals.

b) Alternative:

Combine the "Summary..." into one consolidated submittal to the applicant. This single, consolidated submittal should be more concise than the two separate documents considered together.**

This would permit the staff to identify, in a specific and concise manner, those staff concerns heretofore withheld and is expected to be capable of achieving the same improvement identified in the first alternative, above.

This may create three separate documents. The consolidated identification of requirements would be substituted for the "Comments..." presently submitted. It is suggested that the title be changed to "Commentary...".

Follow-up and submittal to the public record system should be the same as in the first alternative.

^x See Tab A herein.

^{**} See Tab B herein.