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101.1

AUG 31 1983

MEMORANDUM FOR: Raymond F. Fraley, Executive Director
Advisory Committee on Reactor Safeguards

FROM: Robert E. Browning, Acting Director
Division of Waste Management

SUBJECT: ACRS WASTE MANAGEMENT SUBCOMMITTEE COMMENTS ON THE DOE SITE CHARACTERIZATION REPORT (SCR) AND THE NRC DRAFT SITE CHARACTERIZATION ANALYSIS (SCA) FOR THE BASALT WASTE ISOLATION PROJECT AT HANFORD

Thank you for transmitting the May 31, 1983 comments of the ACRS Waste Management Subcommittee. We appreciate this opportunity to interact with the ACRS with respect to the high-level waste, geologic repository program.

The Subcommittee comments have been reviewed by the NRC staff, and the responses are attached. The staff substantially agrees with the concerns expressed by the Subcommittee. Most are issues related to the DOE program of site investigations and we believe they parallel comments that we have made in NUREG-0960 (the BWIP Draft Site Characterization Analysis). References in our response are made to specific sections of NUREG-0960 where appropriate.

In presenting responses to the comments it was deemed best to repeat the Subcommittee text in total. For convenience in linking response to comment, the text was separated (without modification of syntax) into units of related material. Each unit is followed by the related response.

We have paid special attention to Subcommittee comments on the need for some prescription of "acceptable levels of uncertainty (precision and accuracy)" (Attachment item 3ii) and definition of what "tradeoff" considerations would be acceptable (Attachment 2ii). We hope our description of the process by which we expect these will be defined addresses the Subcommittee concerns.

We would be happy to provide additional information on any Subcommittee comment, or staff response, if you desire. We will be able to provide additional information on our comments during the Subcommittee's

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NAME	KWestbrook	RWright	HJMiller	MBell	REBrowning		
DATE	08/ /83	8/ /83	8/ /83	8/ /83	8/ /83		

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scheduled meeting in Richland on September 8 and 9, 1983. The person to contact for additional information is Dr. Robert Wright on 427-4674 or Mr. Paul Prestholt on 427-4597.

Original Signed by
Robert E. Browning

Robert E. Browning, Acting Director
Division of Waste Management

Attachment:
Staff Response to ACRS Waste
Management Subcommittee Comments

cc: R. C. Tang
D. Moeller
L. Olson

See attached list for distribution

BELL COMMENTS INCORPORATED
IN DOCUMENT ON AUG 19, 1983

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Subcommittee

I. General Comments

GC1.

(i) "One of the most striking facts brought out by these meetings was the critical need for a full exchange of data and information among the several groups involved in preparing and reviewing the Site Characterization Report (SCR). Although representatives from both DOE and NRC acknowledged the need for communications and although the channels appear to be improving, more dialogue needs to occur on a regular basis. This was exemplified by the fact that some of the information presented at this meeting was apparently being heard by DOE and/or NRC personnel for the first time. It must be recognized that NRC's role is to require that the site be characterized to the extent necessary for licensing and that this characterization be supported by adequate data. It is DOE's responsibility to be responsive to NRC's requests to the extent practicable. As in the case of this meeting, the ACRS is pleased to foster the necessary exchanges and interactions, to the extent that it can. The Subcommittee plans to continue to interact with both groups and to offer advice as requested".

R1.

We agree. To focus on these needs, we have developed a DOE/NRC interagency procedural agreement dated June 27, 1983 (Attachment 1). The positive effects on information flow since implementation of this agreement are already noticeable.

GC2.

(i) "The limited resources available to both DOE and NRC make it necessary to structure the schedules for data acquisition and analysis very carefully. Both the NRC Staff and the DOE/Contractors should be urged to organize their requests for data and the plans for obtaining such data on the basis of the priorities required by the licensing process. The Subcommittee heard comments that such organization would be desirable but little evidence was presented to show progress toward this objective".

(ii) "Since, in the final analysis, it is the overall performance of the repository that must meet the NRC criteria, certain tradeoffs among individual components of the system will undoubtedly be necessary. To the extent practical, the Staff should seek to define the tradeoff configurations that would be acceptable".

R2(i).

We agree. There is the need to organize comments on the DOE Site Characterization program in a manner which (a) can be related directly to

licensing information needs and (b) conveys a sense of relative importance and priority. The staff review was conducted with this in mind as described in NUREG-0960; the introductory statement to the summary and conclusions (page xi - Attachment 2) explains this.

More specifically, in reviewing the BWIP SCR and developing NUREG-0960, the staff took the following parallel steps, as described in NUREG-0960 and discussed briefly during the April Subcommittee meeting:

Systematic Licensing Issue Assessment - To assure that its review of the SCR was complete and consistent from one technical area to the next, and that concerns raised about the SCR were relevant, the staff did a systematic analysis of 10CFR60 performance requirements and criteria. This was done to identify what specific information would be needed to perform the compliance determination assessments that will be required by DOE in submitting a license application and independently performed by the NRC staff in its licensing reviews. The results of this analysis were presented in NUREG-0960, Appendix C and were used as the basic framework for staff review of each technical area of DOE's Site Characterization program. Appendix C included a rating by the staff of the importance of potential licensing concerns based on our judgment. Additional, more specific but important points about the approach taken in this effort are in a highlighted excerpt from Appendix C (Attachment 3).

Organization and Format of NUREG-0960 - NUREG-0960 was organized to present comments in a way that shows their relative importance. This was done because it was recognized that the systematic effort to be complete in identifying licensing information needs and in commenting on the site characterization plan would potentially result in a large volume of comments. The following summarizes the organization of NUREG-0960:

- Summary and Conclusions - This contains, in pages xvi to xx, the 19 key conclusions about the proposed site characterization program; each conclusion is linked (by reference) to a discussion in Chapters 3-10.

- Chapters 3 to 10 - These provide a discussion of important comments on the site characterization program in each of the major technical areas involved, including the 19 key conclusions.

- Appendix B - To help DOE in preparing future submittals, the staff presented in tabular form, a very detailed set of comments on the presentation of material in the SCR, such as inconsistencies, irregularities in data presentation, contradictions, etc.

- Detailed Technical Appendices - Extensive evaluations of selected technical concerns.

Quantitative Systems Performance Assessment - As described in the presentation before the Subcommittee (April Subcommittee meeting transcript pp 438/439), the staff attempted to perform a fully rigorous, quantitative uncertainty assessment of systems performance. Specifically, with the use of existing data and understanding of DOE conceptual designs, an attempt was made to quantify existing uncertainties with regard to performance of each repository system component and establish the importance of these uncertainties to overall system performance. This included consideration of waste form and package, engineered barriers, and aspects of natural components of the repository system such as hydrology and geochemistry.

The intent was to clearly establish in quantitative terms the relative importance to overall systems performance of concerns being raised by the staff. However, after a substantial staff effort, the attempted uncertainty assessment proved to be impracticable. The uncertainties with respect to far field hydrology prevented use of a single conceptual or mathematical model for the Hanford site which would permit integrating the various repository system components and relating their performance to overall systems performance (i.e., release of radionuclides to the accessible environment - See Chapter 3 and Appendix D). Essentially, we lack enough information to develop and apply a model which will permit integration at the first level in our "logic-tree" of licensing information needs shown by the logic tree schematic diagram (see Attachment 4).

While a quantitative uncertainty assessment of the overall system proved to be impracticable at the current stage of DOE investigations, a more limited quantitative uncertainty assessment of groundwater travel time was completed with respect to hydraulic parameters. This was done because of the importance of the groundwater system to meeting repository system performance requirements. This assessment, presented in Appendix D, was used to support NRC comments on groundwater information requirements and to stress the need for not ignoring or deemphasizing the development and supportive testing of engineered systems. The essential role of sensitivity studies in the systematic, iterative, process of identifying specific licensing information needs is spelled out in Chapter 9 of the NUREG-0960 (Section 9.1.3 and Figure 9.1, excerpts of which are provided in Attachment 5). While the ability to conduct rigorous quantitative sensitivity assessments of the overall system in a manner that fully reflects uncertainties in the various parameters that are likely to affect performance has proven to be impracticable, given current information, the NRC (as well as DOE) will perform them on an ongoing basis as additional data is gathered.

R2(ii).
We agree. The staff should work toward clarification of tradeoff considerations. At the same time, it is necessary to be consistent with the views of the Commission, which, in issuing its final regulations has

given flexibility, to permit tradeoffs among repository components. Along with the increased flexibility goes responsibility for DOE to propose appropriate tradeoffs. It would be inappropriate, and indeed inconsistent with the Commission's final rulemaking action, for the staff to now be defining specific tradeoff configurations that would limit DOE's flexibility.

The staff expects that through the process of (a) following on a close, continuing basis the results of DOE data gathering, and (b) continuing attempts to use these results in independent, quantitative uncertainty assessments of the overall system and system components, we will be in a position to evaluate acceptability of the tradeoffs that DOE ultimately proposes.

GC3.

(i) "In identifying data needs, the Staff presented an overly-detailed list of topics. In many instances this list is of limited utility because of several factors, all of which must be rectified. The Staff should identify in specific terms those data needs that have arisen because of the inadequacy or incompleteness of the information forwarded to them by DOE/Contractors. The Staff should be particularly careful not to request specific but secondary data that contribute to an increase in general knowledge but may do little to increase confidence in site-specific information".

(ii) "The NRC Staff should be urged to follow the practice of specifying as exactly as possible the data needs, the acceptable levels of uncertainty (precision and accuracy) and, only where critical, the methodology. The DOE/Contractors should be free to obtain these data by any appropriate method, but must be prepared to rigorously defend their quality and be prepared to furnish a full range of information to the reviewing NRC Staff. The steps outlined by the Staff at the Subcommittee meeting for correcting these problems appear to be reasonable".

R3(i).

To avoid a situation where concerns and comments were raised without any sense of relative importance being ascribed to them, the staff took specific steps, described above in reponse to comment 2(i). While the staff has adopted a systematic, "logic-tree" approach to developing its concerns (NUREG-0960 Appendix C), these steps are constrained at the current stage of investigation and design development to being qualitative and judgemental in nature.

We have conducted, and will continue to conduct, quantitative sensitivity studies utilizing current site data and information on DOE designs to avoid putting "marginal" or "secondary" issues on an equal footing with information needs of primary importance. Until DOE can be more definitive in what its plans are with respect to reliance on natural system components and development of engineered system components -- on

how DOE plans to allocate performance to various components of the system -- the staff cannot put the relative importance of specific licensing information needs in exact, quantitative terms.

We will continue to conduct our reviews utilizing a systematic, qualitative "logic-tree analysis" of repository system performance supplemented by quantitative sensitivity studies of the system. (See NUREG-0960 Chapter 9, Pages 9-2 to 9-4).

R3(ii).
To avoid contradicting the Commission's final rulemaking which provided flexibility to the DOE in allocating performance objectives to repository system components, the staff may not be in a position to prescribe acceptable levels of uncertainty (precision and accuracy). At the present stage, it would be arbitrary for the staff to do so given the current large uncertainties about important aspects of the repository system (e.g., fundamental aspects of groundwater flow such as flow paths and travel times, where uncertainties encompass many orders of magnitude - See Appendix D).

The NRC staff has taken the position, with respect to the BWIP, that it is more appropriate for the DOE to make decisions about the allocations of resources to the development and supportive testing of the various components of the overall system. The DOE is uniquely responsible for considering all of the factors which must be taken account of in developing the repository. In addition to the technical questions involved in this complex, first-of-a-kind project, availability of resources, schedule and other programmatic requirements must be considered.

As more definitive decisions are made by the DOE about what it will be attempting to demonstrate with reasonable assurance with respect to performance of each aspect of the repository system -- both engineering and natural system barriers -- it may be possible to arrive at a definition of how many of what kind of tests will be required. This is particularly true of testing of engineered components and complex near-field phenomena. As a consequence, the position of the staff, as expressed in the NUREG-0960 (Chapter 7 and Summary and Conclusion comment 12 - Attachment 6), is that the DOE should present its plans in terms of interim subsystem performance requirements which it has established in making programmatic decisions. These will assist us in commenting on the appropriateness of tradeoffs being proposed and be exact on final licensing information needs.

For the actual testing to be performed over the next year or so (i.e., the initial steps of DOE's site characterization program), the systematic, albeit largely qualitative, process of licensing information needs identification described above should be sufficient.

GC4.

(i) "It is clear that information on data collection and treatment must be made readily and completely available to the Staff. The Subcommittee was disturbed to hear that some of the data presented by DOE/Contractors to the NRC may not have been of the quality that it appeared to be. Closer and more effective interaction between the Staff and the DOE/Contractors is necessary to avoid such problems".

(ii) "The Subcommitte found inadequate evidence that the models used in estimating certain repository behavior and impacts were sufficiently verified by experimental data. As the process of repository selection and corresponding analyses proceeds, such model verification will become increasingly important".

(iii) "The NRC Staff should be urged to provide information derived from sensitivity studies to guide its own research, and to communicate to DOE/Contractors the importance of selected data and requests for them. Through such an approach, the Staff may be able to define the levels of uncertainty that are called for under item 3 above".

R4(i).
We agree. NRC staff comments have been made to DOE in NUREG-0960, and during subsequent discussions on quality assurance and data availability. We have published a draft technical position paper specifically on quality assurance. We anticipate improvements in data release by DOE as a result of our increased interactions in this area.

R4(ii).
We agree. We believe this is addressed in NUREG-0960, pages 9-14 and 9-15.

R4(iii).
We agree. There is the need to conduct sensitivity studies to guide NRC research activities as well as to aid in defining licensing information needs to the DOE. Notwithstanding limitations on the ability to conduct such "uncertainty" assessments at the current stage of investigation at the BWIP (as described in answer to 2 and 3 above), continuing to attempt such assessments is a major part of NRC's activities in support of the prelicensing consultation process as described in NUREG-0960, Chapter 9, Section 9.1.3.

GC5.

"The requirement that the retrievability option be maintained may negate prompt backfilling of the waste emplacement holes. This, in turn, could exacerbate the potentiality for water (and steam) interaction with the waste canisters and subsequent degradation due to corrosion. Although the requirement for retrievability is

incorporated into the EPA proposed environmental release standards, it is the Subcommittee's impression that this should apply primarily to correcting mistakes that might occur during waste emplacement, rather than facilitating removal of wastes from a repository which later proves to be unacceptable. If unprocessed spent fuel is placed in the repository, retrievability should be maintained until it can be made certain that there is no need to recover the uranium and plutonium for future use".

R5.

The Commission's position is to require that the option of waste retrieval be maintained throughout the period during which the wastes are being emplaced, and, thereafter, until the completion of a performance confirmation program and Commission review of the information obtained from such a program. The purpose of this position is to protect public health and safety in the event the site or design proves unsuitable. The provision for retrievability is not intended to facilitate recovery for resource value. The Commission has no authority to protect the recoverability of nuclear energy resources for possible future use. (See "Supplementary Information to 10CFR60, FR June 21, 1983, pages 28197 and 28198).

GC6.

"Commentary:

Three additional items appear worthy of comment:

a. Both DOE and NRC Staff members now agree that obtaining the necessary site-specific data for BWIP may require additional drilling on site. Although care will have to be taken to assure proper selection of such drill holes, and proper plugging and sealing of them after the tests have been completed, this now does not appear to be a problem.

b. The work load placed upon the NRC Staff in reviewing the SCR for the proposed basalt repository has been demanding. Estimates are that this review has required about 12 person-years. With SCRs soon to be prepared for additional proposed repositories (i.e., in tuff, salt and perhaps granite), the question arises whether the NRC Staff will be able to meet the associated commitments. This matter needs to be carefully assessed and appropriate plans must be developed. Included in such planning should be a careful selection and grouping of the key items to be addressed. Time does not permit the direction of efforts to matters of minor importance.

c. To facilitate the review and understanding of the Site Characterization Analysis prepared by the NRC staff, greater care needs to be directed to their format. The current draft

appears to deal in so much detail that the overall concerns and interests of the NRC staff could be missed. Critical issues and specific recommendations should be highlighted".

R6a.
We agree. The needs for further drilling are indicated in NUREG-0960, page 4-7, paragraph 3; page 4-8, paragraph 1 and 2; page 4-9, paragraph 4; page 4-10, paragraph 4 and paragraph 5. Partly as a result of this documentation, DOE also recognizes the need for more exploratory drilling. With respect to the important area of groundwater investigations, the staff has produced a draft technical position paper which served as the basis for obtaining specific agreements with DOE on construction and testing of additional boreholes. This agreement was reached in an NRC-DOE technical meeting in July 1983. With respect to the long-term sealing of boreholes, the staff considers that additional testing and analyses are required. Specific needs were identified in NUREG-0960, Section 6.3.3. Given the importance of this matter, the staff has also issued a draft generic technical position on repository shaft and borehole sealing.

R6b.
We agree. We have identified additional resource needs based on extensive analyses of the activities required in connection with all DOE sites. Resources are already being allocated to pre-SCP (Site Characterization Plan) communication and coordination with DOE on these additional sites. This staff interaction with DOE prior to the receipt of Site Characterization Plans should assist us in selecting and grouping the key items to be addressed.

R6c.
We agree. NUREG-0960 was prepared to be complete and at the same time to present analyses in such a way that major concerns were not missed and each reader could find the level of detail desired. In our future site characterization documents we plan a more effective description of how the contents are organized.

Subcommittee

II. Technical Comments:

TC1.

"Overall, this review revealed a lack of certain detailed data about the candidate site. This was exemplified by many factors including the need for a better understanding of the Nancy lineament, the groundwater barrier that creates the large difference (approximately 400') in hydraulic head between confirmed aquifers of the proposed site and zones to the northwest. Data are also lacking on the basalt flow thicknesses and properties within the site, and permeable fracture zones within the site. No firm geological, hydrological and geophysical projections can be made for the necessary thousands of years into the future without site-specific information. The current acceptability of additional drilling onsite should expedite the acquisition of the required data".

R1.

We agree. NRC staff comments have been made to DOE in NUREG-0960, and during numerous discussions on a broad range of topics, to the effect that information is lacking to support the level of confidence expressed in the SCR about site suitability. Present site characterization plans, as we have been able to take them up in technical meetings held with DOE, (since NUREG-0960) are better directed toward gathering the information needed for licensing than the program presented in the Site Characterization Report.

TC2.

(i) "Earthquakes within the site area may continue and may even originate within the repository. Data are needed on the seismic moment (and therefore fracture size) of known earthquakes in the area".

(ii) "Extensive experience beginning with the Denver earthquake a few years ago shows that earthquakes can be turned on and off by pumping water into or out of the ground, respectively. This happens because the critical shear stress necessary for a fracture to slip is a function of the effective stress (the normal stress minus the fluid pore pressure). Thus, one would expect earthquakes to be suppressed by dewatering of the site and to be triggered by its subsequent re-flooding. This whole realm needs to be analyzed even though the earthquakes known to be induced are insignificantly small. Because in situ stresses have been measured, there is a real opportunity to develop a range of failure models and thus to anticipate future problems".

R2(i).
We agree. We have indicated a need for more data related to earthquakes in NUREG-0960; page 4-9, paragraph 3; page 4-10, paragraph 1, section 4.5.; and paragraph 5; page 4-6, paragraph 1, paragraph 2, paragraph 5; and Appendices M,N,O.

R2(ii).
We agree. We believe that the question of the effects of dewatering and subsequent reflooding of the repository related to earthquakes needs to be addressed. However, this comment implies that earthquakes are suppressed by dewatering and triggered by reflooding. We do not fully agree with this implication because water can act as a lubricant allowing frequent small movements which could prevent the build up of stresses from reaching the brittle failure point of rock masses. It is possible that dewatering itself could cause decreases in microseismic activity resulting in less frequent, but potentially much more intense, movements. Earthquake problems are difficult to model and the results of such models, while useful for general understanding of potential seismic changes that are likely, can not be considered to have high reliability or accurate predictive capabilities.

On August 17-18, 1983, the staff met with its contractors on modeling seismo-tectonic impacts on underground repositories. The purpose was to discuss developing the capability to assess uncertainties on rock failure models of a predictive nature. We intend to ensure that reasonable efforts are made by DOE to investigate the various scenarios which could develop and to ensure comprehensive seismic monitoring. We will discuss these matters with DOE in future meetings on seismology and hydrology.

TC3.
"Site Specific Data:

a. <u>Rock Permeability, Strength, and Stratigraphic and Structural Continuities</u>

Site-specific data are needed to support the feasibility of the conceptual repository design. Among these are: the strength, structure and stratigraphic continuity of the rock and the presence or absence of water and its flow. Additional core borings both vertical and inclined need to be drilled to determine the frequency, character and attitude of the vertical and steeply dipping joints within the limits of the repository as planned. Physical testing needs to be performed of the rock core at temperatures to be developed by the waste and at the existing water content. The strength and continuity of the rock mass at the level of the repository also needs to be determined. The permeability of the rock mass as well as the repository layer should be established by full-scale, well instrumented, long-duration pumping tests with observation

wells drilled specifically for this purpose in the repository site beneath the Umtanum flow. Permeabilities of critical zones should be established.

R3a.
We agree. The need for this information is expressed in several parts of NUREG-0960: Chapter 3 - determination of bulk permeability; Chapter 4 - rock structure and jointing system; Chapter 6 - rock strength and the effect of discontinuities; and Appendix B - rock strength, joint systems, rock structure and discontinuities.

"b. Geochemistry/Waste Package Design

(i) The Subcommittee observed that while the nature of the geochemical interactions between the waste package components and the geologic formations is complex, the DOE/Contractors' treatment appeared to avoid major issues that were subsequently and appropriate raised by the NRC Staff. Impressions gathered from the SCR were that some important conclusions were drawn on the basis of insufficient data or, in some cases, no data at all.

(ii) The Subcommittee also noted that some aspects of the NRC Staff presentation concerning geochemistry appeared to be peripheral to the important questions. The Staff should be urged to focus sharply on the identified data needs that will directly address questions of radionuclide transport.

(iii) The DOE/Contractors should be required to increase the visibility of their methodology and data significantly, and to demonstrate explicitly that certain potential effects (e.g., transport of actinides by dissolved organic groundwater components) can be neglected.

(iv) The Subcommittee also recommends that the issues surrounding radiolysis be examined in a detailed manner. Prior to backfilling (and without massive ventilation) the canisters may be in an extremely corrosive environment, since radiolysis of air and water produces several potentially corrosive products. Even if the emplaced canisters are backfilled promptly, radiolysis can still produce corrosive products if water saturates the backfill. The impact of such reactions on the canister integrity requirement should be evaluated".

R3b.
(i) We agree. Please see the response to Section II technical comments, Item 1, above.

(ii) This comment is noted for use in future presentations. It is certainly the intent that NUREG-0960 should focus on "the identified data needs that will directly address questions of radionuclide transport." Specifically, the matter is addressed in NUREG-0960, paragraph 2. on page 5-4 and on the five pages following, with respect to radionuclide transport data needs.

(iii) We agree. One of the main comments that we made on DOE's Site Characterization Report is the need to identify in advance the plans for testing and the methodology of the tests. This will lay the basis for us, and the interested public, to track the progress in site characterization activities. With reference to geochemical work, the need for knowledge about planned tests and experiments is expressed in NUREG-0960, pages 5-13 and 5-14.

(iv) We agree. The importance of the radiolysis effect is an open question at the present state of knowledge. While some testing has been done, it is largely qualitative and more quantitative work is needed. Also, the importance of the radiolysis effect is influenced by canister design: a shielded container could temper, or eliminate, the effect of radiolysis. This is an option that is available to DOE. In NUREG-0960 the effect of radiolysis on chemical conditions and the environment surrounding the canister is discussed in paragraph 7.3.5.1, page 7-10; the effect of radiation on canister corrosion is treated in Appendix P; the enhancement of corrosion, due to trapping of radiolysis products by backfill, is described on pages P-6 and and P-10 of Appendix P.

TC4. "Repository Design

a. Selection of the Rock Horizon for the Repository

(i) Neither the DOE Site Characterization Report nor the NRC Site Characterization Analysis deals with selection of the rock horizon for the repository. No detailed information on water bearing characteristics or on horizontal or gently dipping heterogeneities which may occur in either of the two candiates flows (the Cohasset above, or the Umtanum, below) has been provided. If such planes of weakness occur in these flows, then the roof of the repository should be so located that it is not affected. To permit ease of excavation and safer working conditions, the repository should be located in solid rock, if such is available. The repository horizon should be essentially dry.

(ii) The detailed description of the geological section of the rock layer in which the repository will be located is a fundamental necessity for its proper design. Therefore, extreme care needs to be shown in the logging of the core and description of the drilling of the borings penetrating

the zone of the repository. The rock characteristics should be checked on a face-to-face basis in the exploratory shaft. The location of the repository should be established on the basis of detailed logging of the walls of the shaft so that the roof of the repository will be within a massive layer of basalt to provide a stable crown over the repository. This logging requires that the lining of the shaft in the repository zone be delayed until the logging of the walls of the shaft in the critical zones is complete".

R4a.
(i) We agree. DOE needs more information on candidate horizons to make a sound decision on which to base further site characterization. Please see our response to Section II, Item 1, above.

(ii) We agree. The repository host rock needs to be well characterized for proper repository design. This is being approached by DOE through the examination and testing of rock cores, hydrologic testing geophysical logging of boreholes and, most important, an examination of large underground openings.

While examination of the shaft wall would be desirable, this is precluded by DOE's choice of the method for shaft construction (i.e. blind boring and casing immediately to total depth). The NRC staff has reviewed the BWIP shaft construction alternatives with DOE beginning in September 1981 with respect to the related, and in some cases competing, factors that must be considered: (a) gathering of geologic information, (b) safety of shaft construction and operation, (c) long-term shaft sealing, and (d) basic feasibility. We have concluded that the factors arguing for the blind boring approach (such as the need to control potentially large volumes of high pressure water in the flow tops) outweigh the limited additional information that might be gathered beyond what will be gathered by the other methods described above.

"b. <u>Repository Depth and Orientation</u>

(i) The repository needs to be deep enough so that it is adequately safe from inadvertent penetration or unusual erosion. But it does not need to be deeper than this unless good rock is unavailable at shallower depths. Selection of a deeper than necessary horizon will increase the costs of access, hoisting, pumping and air conditioning.

(ii) Orientation of the repository should be such that maintenance and operating conditions will be as simple as possible. To accomplish this goal, the placement rooms should be oriented parallel to the maximum principal horizontal stress on their walls. Such an orientation

would place the canister holes parallel to the lesser principal horizontal stress.

R4b.
(i) We agree. Selection of repository horizon will involve balancing a variety of factors including cost. In any case, the rock must have adequate strength, permeability, lateral extent, and thickness.

(ii) We agree. To optimize the orientation of waste placement rooms, detailed analysis must also consider the anomalies, in the stress field caused by the haulageways, rooms, and other openings into the host rock.

"c. Shaft Diameters and Roof Spans

(i) Shafts of one design would reduce the cost of drilling machines and allow the use of common facilities. The high velocities of ventilation air, approaching 20 miles per hour, make the service shaft an undesirable personnel route.

(ii) The underground openings (shown in Fig. 10-8 of the SCR) will provide intersections where the roof span may approach the limit which the basalt can support. Reduction of the radius of the intersections may be of value. The support system for the roof should be at or embedded in the roof, probably in the form of roof bolts. Several patterns of bolting should be examined before specifying final requirements".

R4c.

(i) We believe that this is a matter for DOE to decide.

(ii) We agree. DOE will be required to demonstrate the acceptability of proposed designs and support systems. In developing designs, after gathering required data on rock mass properties, DOE will have to consider factors such as radii of intersections and the need for rock bolts and other forms of rock support.

"d. Exploration and Testing

It would appear that exploration of certain aspects of the proposed repository design could be investigated within Gable Mountain. These include:

1) Canister hole drilling over a range of diameters, including back reaming;

2) Backfilling of waste holes after placement of canisters;

3) Retrievability of canisters from the waste holes;

4) Placement of proposed backfill material in repository rooms".

R4d.
We agree with all 4 items. Useful investigations can be done which are basically applicable to the proposed repository. Due to different stress conditions and groundwater conditions, the need for in situ testing at depth in the actual candidate location will remain.

Background

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

June 15, 1983

William J. Dircks
Executive Director for Operations

Attn: T. Rehm

Subj: 277TH ACRS MEETING FOLLOW-UP ITEMS

Based on discussions regarding methods for improved implementation and followup of ACRS recommendations, the Committee agreed that a summary of Actions, Agreements, Assignments, and Requests made during each full Committee meeting will be sent to your office following each meeting.

Attached per this agreement is a list of the requests made at the 277th ACRS Meeting, May 12-14, 1983. This list has the concurrence of the ACRS Chairman and designated ACRS Members.

Those items in the list "Actions, Agreements, Assignments, and Requests" dated June 6, 1983 that do not deal with requests made of the NRC Staff or that are not pertinent to NRC Staff activities have not been included in this followup list.

R. F. Fraley
R. F. Fraley
Executive Director

cc C. J. Heltemes, AEOD
H. R. Denton, NRR
R. B. Minogue, RES
R. C. DeYoung, I&E
J. G. Davis, NMSS
E. G. Case, NRR
ACRS Members

R.C. Tang

Attachments: As stated

• address to either subcommittee or to Fraley

FOIA Exemption (b)(5)

ACTIONS, RECOMMENDATIONS, AND REQUESTS
277TH ACRS MEETING, MAY 12-14, 1983

ACRS Report on the Systematic Evaluation Program Review of the LaCrosse Boiling Water Reactor

1. The Committee prepared a report to the Commissioners of its review of the results of the Systematic Evaluation Program, Phase II, as it has been applied to the LaCrosse Boiling Water Reactor. The Committee deferred its review of the FTOL for the LaCrosse Plant until the Staff has completed its actions on the remaining SEP topics and the USIs and TMI Action Plan items. A copy of this report is attached.

NRR

ACRS Report on the Systematic Evaluation Program Review of the Haddam Neck Plant

2. The Committee prepared a report to the Commissioners of its review of the results of the Systematic Evaluation Program, Phase II, as it applied to the Haddam Neck Plant. The ACRS expects to review further the design bases for protection against external events, and wishes to review the resolution of the remaining issues when the supplemental report is available. This report is appended.

NRR

Final Rules on Immediate Notification Requirements (10 CFR 50.72) and Licensee Event Reporting (10 CFR 50.73)

3. The Committee prepared a report to the Commissioners of its consideration of the proposed final rules on Immediate Notification Requirements and Licensee Event Reporting (LER) system. The ACRS believes that as a complement to the new LER system, it is essential to have an effective Nuclear Plant Reliability Data System (NPRDS) to collect information related to the failure rates of safety-related components used in nuclear power plants. The Committee wishes to be kept informed of the progress toward implementing NPRDS and informed by the NRC Staff when both the LER system and NPRDS are working in concert. A copy of this report is attached.

AEOD

ACRS Action on Proposed Regulatory Guide on Instrument Sensing Lines (Task No. IC 126-5)

4. The Committee prepared a letter to the EDO in which it concurred in the Regulatory Position of the proposed Regulatory Guide on Instrument Sensing Lines (Task No. IC 126-5), dated November 8, 1982. The ACRS recommends that the operating plants be examined for instrument lines in those plants in which inappropriate combinations of transducers are connected to common instrument lines to verify that failure of such lines would not cause unacceptable consequences. This report is appended.

NRR

ACTIONS, RECOMMENDATIONS, AND REQUESTS
277TH ACRS MEETING, MAY 12-14, 1983

ACRS Report on Regionalization

NRR

5. The Committee prepared a report to the Commissioners of its concerns regarding the plan for regionalization of certain NRC operations. A copy of this report is attached.

ACRS Report on the Accident Sequence Precursor Study and the Use of Operating Experience

RES

6. The Committee prepared a report to the EDO of its review of some of the recent work and proposed programs related to the evaluation and use of operational experience, including the possible identification of accident sequences likely to lead to core damage as contained in NUREG/CR-2497, "Precursors to Potential Severe Core Damage Accidents: 1969-1979, A Status Report," Volumes 1 and 2. This report is attached.

Use of Potassium Iodide (KI) as a Thyroid Blocking Agent

RES

7. The Committee endorsed the sending of (but did not formally approve) summary comments of the Reactor Radiological Effects Subcommittee based on its discussions with the NRC Staff, as well as representatives of the Food and Drug Administration (FDA) and the National Council on Radiation Protection and Measurements (NCRP) on the issue of stockpiling and predistribution of potassium iodide for potential nuclear power plant accidents. A copy of these summary comments is appended.

Control Room Habitability

NRR

8. The Committee endorsed the sending of (but did not formally approve) summary comments of the Reactor Radiological Effects Subcommittee regarding followup discussions with the NRC Staff on the subject of Control Room Habitability. These summary comments are attached.

Comments on the DOE Site Characterization Report and the NRC Draft Site Characterization Analysis for the Basalt Waste Isolation Project

NMSS
WM

9. The Committee endorsed the sending of (but did not formally approve) summary comments of the Waste Management Subcommittee and its consultants regarding review of the DOE Site Characterization Report and NRC's draft Site Characterization Analysis for the proposed basalt high-level waste repository at Hanford. A copy of these comments is attached.

Cost Benefit Analyses of Proposed Regulatory Requirements

DEDROGR

10. During the report of the May 13, 1983 combined ACRS Subcommittee Meeting on Reliability and Probabilistic Assessment and Extreme External Phenomena at the 277th ACRS Meeting, Acting Chairman J. Ebersole mentioned a lengthy document in draft form being assembled

by T. E. Murley of the DEDROGR's office which uses total cost/total benefits as a scheme for doing cost-benefit analyses. He requested that a copy of this report, or at least a summary of the information be provided to the ACRS for information.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

June 3, 1983

MEMORANDUM FOR: Waste Management Subcommittee Members and Consultants

FROM: R. C. Tang, Staff Engineer

SUBJECT: SUBCOMMITTEE COMMENTS ON THE DOE SCR AND THE NRC DRAFT SCA FOR THE BWIP AT HANFORD

The subject subcommittee comments have been forwarded to the NRC and DOE Staff on May 31st. A copy is enclosed for your information.

Enclosure:
As stated

cc: W/O Enclosures:
ACRS Staff:
J. C. McKinley
R. Fraley
M. Libarkin

ATTACHMENT 1

ATTACHMENT 1.

PROCEDURAL AGREEMENT BETWEEN THE U.S. NUCLEAR REGULATORY COMMISSION AND THE U.S. DEPARTMENT OF ENERGY IDENTIFYING GUIDING PRINCIPLES FOR INTERFACE DURING SITE INVESTIGATION AND SITE CHARACTERIZATION

This Procedural Agreement outlines procedures for consultation and exchange of information which the Commission (NRC) and the Department (DOE) will observe in connection with the characterization of sites for a geologic repository under the Nuclear Waste Policy Act of 1982. The purpose of these procedures is to assure that an information flow is maintained between the two agencies which will facilitate the accomplishment by each agency of its responsibilites relative to site investigation and characterization under the National Waste Policy Act (NWPA). The agreement is to assure that NRC receives adequate information on a timely basis to enable NRC to review, evaluate, and comment on those DOE activities of regulatory interest in accordance with DOE's project decision schedule and thereby facilitate early identification of potential licensing issues for timely staff resolution. The agreement is to assure that DOE has prompt access to NRC for discussions and explanations relative to the intent, meaning and purpose of NRC comments and evaluations on DOE activities and so that DOE can be aware, on a current basis, of the status of NRC actions relative to DOE activities.

This Procedural Agreement shall be subject to the provisions of any project decision schedule that may hereafter be established by DOE, and any regulations that may hereafter be adopted by NRC, pursuant to law. In particular, nothing herein shall be construed to limit the authority of the Commission to require the submission of information as part of a general plan for site characterization activities to be conducted at a candidate site or the submission of reports on the nature and extent of site characterization activities at a candidate site and the information developed from such activities.

1. NRC On-Site Representatives

   As early as practicable, following area phase field work, NRC on-site representatives will be stationed at each site undergoing investigation principally to serve as a point of prompt informational exchange and consultation and to preliminarily identify concerns about such investigations relating to potential licensing issues.

2. Meetings

   From the time this agreement is entered into, and for so long as site characterization activities are being planned or are in

progress, DOE and NRC will schedule and hold meetings periodically as provided in this section. A written report agreed to by both DOE and NRC will be prepared for each meeting including agreements reached.

a. Technical meetings will be held between DOE and NRC-technical staff to: review and consult on interpretations of data; identify potential licensing issues; agree upon the sufficiency of available information and data; and agree upon methods and approaches for the acquisition of additional information and data as needed to facilitate NRC reviews and evaluations and for staff resolution of such potential licensing issues.

b. Periodic management meetings will be held at the site-specific project level whenever necessary, but at least quarterly, to review the summary results of the technical meetings; to review the status of outstanding concerns and issues; discuss plans for resolution of outstanding items and issues; to update the schedule of technical meetings and other actions needed for staff resolution of open items regarding site characterization programs; and to consult on what generic guidance is advisable and necessary for NRC to prepare. Unresolved management issues will be promptly elevated to upper management for resolution.

c. Early technical meetings will be scheduled to discuss written NRC comments on DOE documents such as Site Characterization Plans, DOE's semi-annual progress reports, and technical reports to foster a mutual understanding of comments and the information or activities needed for staff resolution of the comments.

d. In formulating plans for activities which DOE will undertake to develop information needed for staff resolution of potential licensing issues, DOE will meet with NRC to provide an overview of the plans so that NRC can comment on their sufficiency. These discussions will be held sufficiently early so that any changes that NRC comments may entail can be duly considered by DOE in a manner not to delay DOE activities.

e. Schedules of activities pertaining to technical meetings will be made publicly available. Potential host States and affected Indian tribes will be notified and invited to attend technical meetings covered in this section (Section 2, Meetings). The notification will be given on a timely basis by the DOE. These technical meetings will be open meetings with members of the public being permitted to attend as observers.

3. Timely Release of Information

a. Data collected during site investigations will be made available to NRC on a current, continuing basis after the DOE (or DOE contractor) quality assurance checks that are inherent in determining that the data has been obtained and documented properly.

b. DOE's analyses and evaluations of data will be made available to NRC in a timely manner.

4. Site Specific Samples

Consistent with mutually agreed on procedures, DOE will provide NRC with site specific samples to be used by NRC for independent analysis and evaluation.

5. Agency Use of Information

It is understood that information made available to either Agency under this agreement may be used at that Agency's option in carrying out its responsibilities.

6. Project Specific Agreements

Project specific agreements to implement the above principles will be negotiated within 120 days of the time this agreement is entered into. These project specific agreements will be tailored to the specific projects to reflect the differences in sites and project organizations.

7. Nothing in this agreement shall be construed as limiting forms of informal consultation not mentioned in this agreement (for example, telephone conversation or exchanges of reports). These other consultations will be documented in a timely manner.

R L Morgan

Robert L. Morgan, Project Director
Nuclear Waste Policy Act
Project Office
U.S. Department of Energy

Date: 6/27/83

John G. Davis

John G. Davis, Director
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory
Commission

Date: 6/17/83

ATTACHMENT 2

ATTACHMENT 2.

SUMMARY AND CONCLUSIONS

INTRODUCTION

On November 12, 1982, the U.S. Department of Energy (DOE) submitted to the U.S. Nuclear Regulatory Commission (NRC) the "Site Characterization Report for the Basalt Waste Isolation Project" (DOE/RL 82-3). The Basalt Waste Isolation Project (BWIP) is located on DOE's Hanford Reservation in the State of Washington. In accordance with Part 60.11(d) of Title 10 of the Code of Federal Regulations (cited in this report as 10 CFR 60.11(d)), the staff of the NRC has prepared this draft analysis of the Site Characterization Report (SCR).

The SCR summarizes the results of DOE's investigations to date, describes a conceptual repository design, and presents information on waste form and package designs. It discusses outstanding issues, together with the work elements and general plans for obtaining information to address these issues.

The basic concerns addressed by the NRC staff review of the SCR and the proposed DOE program of site characterization at the BWIP are: (1) will the proposed site characterization program produce sufficient information so the NRC can assess adequacy of the site and the repository design, as part of the licensing process? and (2) are plans adequate to mitigate any adverse effects on waste isolation properties of the site, due to site characterization?

The review of the SCR centered around an analysis of the specific questions that will have to be answered in making licensing assessments. To set the stage for the review, the NRC staff systematically identified those questions (explained in Appendix C of this report). This was done, before the SCR was received, by carefully considering the performance objectives, criteria, and requirements of 10 CFR 60, which was made available in July 1982. The staff also considered preliminary information about the BWIP presented in technical publications and obtained in NRC staff reviews of BWIP activities.

The SCR was then reviewed in terms of licensing information needs: (1) does it adequately identify potential licensing issues?, (2) does it adequately describe the level of knowledge and uncertainty associated with the results of investigations to date?, and (3) are the proposed investigations adequate to obtain the remaining information needed to address the licensing issues?

In general, the contents of the SCR are organized in keeping with the suggestions of NRC Regulatory Guide (RG) 4.17, "Standard Form and Content of Site Characterization Reports for High-Level Waste Geologic Repositories." The present state of knowledge, given in Chapters 1 to 12 of this report, is followed by the identification and characterization of issues, and the program for addressing these issues, in Chapters 13 to 17. Chapter 18 discusses quality assurance, and Chapter 19 describes alternative sites.

ATTACHMENT 3

ATTACHMENT 3.

EXCERPT FROM
NUREG - 0960
APPENDIX C

1 INTRODUCTION

The Basalt Waste Isolation Project (BWIP) Site Characterization Report (SCR) is an issue-oriented document, as specified by the Nuclear Regulatory Commission (NRC) "Standard Format and Content for Site Characterization Reports" (Regulatory Guide 4.17). The Department of Energy (DOE) issues and related work elements provide the framework used to present the site characterization plans in the SCR.

The objectives of NRC's SCR analysis are: first, determine if the SCR adequately identifies the issues at the site; and second, determine if the plans to resolve the issues are adequate. This analysis is intended to ensure that all significant questions relevant to future repository licensing are raised as early in site characterization as possible, so that the site characterization program will produce the information needed to assess the adequacy of the site and repository design during licensing. To aid in the SCR analysis, the NRC independently, and prior to the receipt of the SCR, developed an issues list that provides a framework for the analysis. This issue list also aids in simplifying the complex problem of assessing repository performance by logically and systematically breaking the problem into more manageable parts, so that the interrelationships between parts or between the parts and the performance objectives of 10 CFR Part 60 are clear. This breakdown facilitates integration of the many disciplines contributing to issue analyses and performance assessment. The NRC issues may also provide an organizational structure for tracking DOE site characterization activities.

This appendix gives a complete listing of the issues identified by both NRC staff and DOE. It describes the logic and process that the NRC staff used to identify BWIP site issues and correlates these issues to those identified by DOE in the SCR. Ratings of the BWIP program for each NRC issue are also presented. The NRC issue list in this appendix is a further development of the list first produced in May 1982.

2 DEFINITION OF SITE ISSUES AND REPOSITORY ELEMENTS

A site issue, as used in this report, is a question about a specific site that must be answered or resolved to complete licensing assessments of the site and design suitability in terms of 10 CFR 60. Site issues are not necessarily controversal questions. For the SCA site issues can be divided into performance issues and specific issues. Performance issues are broad questions concerning both the operational and long-term performance of the various elements of the overall geologic repository system (e.g., waste form, waste package; see Figure C-1). Performance issues include the integration of numerous specific issues. Generally, these are questions about conditions and processes (information needed) that must be considered in assessing the performance issues. Specific issues encompass many levels of detail. The use of performance and specific issues does not necessarily reflect degrees of importance in repository performance. It is conceivable that a detailed specific issue could be of equal or greater importance than a particular performance issue. Questions

related to matters such as methods of data collection, data analysis, performance modeling, and performance validation are not considered as issues but, rather, concerns addressed in the analysis of each issue.

The DOE definition of issue used in the SCR is somewhat different in emphasis from NRC's definition given above. This difference should be considered when comparing the two lists of issues. The DOE SCR defines an issue as "...a technical question about which there is debate or controversy. Issues are technical questions that arise when the available information or technology is insufficient to make a specific decision or come to a specific conclusion about some aspect of repository siting or development" (SCR, page 13.0-1). Furthermore, methods of study are considered to be issues. DOE has also defined work elements in the SCR as "...a technical activity required to satisfy all or part of a criterion and/or to resolve an issue identified for siting and/or developing a nuclear waste repository in basalt" (SCR, page 13.0-1). Many of these work elements are similar to the NRC issue statements.

Many of the issues identified by NRC are related to various elements of a geologic repository system. These elements and other terms important to repository performance are defined below and illustrated in Figure C-1. Other terms are defined in Explanation of Frequently Used Terms and Chapter 9.

Accessible environment is (1) the atmosphere, (2) land surface, (3) surface water, (4) oceans, and (5) the portion of the lithosphere that is outside the controlled area.

Backfill is material that might be emplaced in the underground openings of the underground facility other than the emplacement holes, shafts, and boreholes.

Controlled area is a surface location, to be marked by suitable monuments extending horizontally no more than 10 kilometers in any direction from the underground facility, and the underlying subsurface, which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure.

Disturbed zone is that portion of the controlled area whose physical or chemical properties have changed as a result of underground facility construction or from heat generated by the emplaced radioactive wastes such that the resultant change of properties may have a significant effect on the performance of the geologic repository.

Emplacement hole is an opening in the rock directly surrounding the waste package.

Engineered barrier system is the waste package and the underground facility.

Far field is the portion of the geologic setting that lies between the outer edge of the disturbed zone and the accessible environment.

Geologic setting includes the geologic, hydrologic, and geochemical systems of the region in which a geologic repository operations area is or may be located.

Packing is that part of the waste package that is emplaced between the outer container and the rock wall of the emplacement hole.

Underground facility is the underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals.

Waste form is the radioactive waste materials and any encapsulating or stabilizing matrix.

Waste package is the waste form and any containers, shielding, packing, and other components surrounding the waste form.

3 DEVELOPMENT OF NRC ISSUES

Before receiving the SCR, the NRC staff identified a set of issues that systematically considers the required assessments necessary to independently evaluate, during licensing, the performance of proposed a repository. Issues are logically broken down from broad to more specific levels of detail. This breakdown facilitates the focus of the SCR analysis on individual, detailed site characterization plans as well as the integration of plans from the broad view of the overall repository system. The logic and process used for issue identification are illustrated in Figures C-2 and C-3.

As shown in Figure C-3, issue development involves two main stages. First, the site characterization matters are divided into safety assessment and environmental assessment. Second, the safety assessment is subdivided into assessments related to two time periods: through permanent closure (operational) and after permanent closure (long-term). These potential safety issues are derived directly from 10 CFR 60, and the environmental issues are derived from 10 CFR 51. Further issue development entails dividing the performance objectives of 10 CFR 60 into performance issues corresponding to the individual performance of the various system elements. These system elements are shown schematically in Figure C-1 and are defined in Section 2 of this appendix. Table C-1 correlates the performance issues to the performance objectives of 10 CFR 60.

Significant conditions and processes (includes potential adverse conditions of 10 CFR 60) are then identified for each performance issue. These significant conditions and processes are those that (1) exist before repository disturbance, (2) could cause future changes, and (3) result from change. They also fall into the categories of natural (e.g., faulting), repository induced (e.g., thermal buoyancy), and human induced (e.g., withdrawal of water resources). Many conditions or processes are important to more than one performance issue. This duplication of conditions and processes is eliminated by combining similar or repeated conditions or processes into a final set of specific issues. This final set is then divided between five technical review groups (Groundwater, Waste Form/Waste Package, Geochemistry, Repository Design, and Geology). Table C-2 lists all of the performance and specific issues and correlates them to the issues and work elements identified by DOE. These issue statements are numbered and listed by the groups described above. This list should be used as the master reference list of issue statements when particular issues are referenced only by their number in the SCA chapters or appendices.

Table C-3 correlates specific issues to performance issues in a matrix form. This table shows (1) the importance of specific issues to repository performance, (2) how specific issues are integrated to address each performance issue, and (3) how any single specific issue might contribute to assessing more than one performance issue. For example, investigations of faults and fractures (specific Issue 5.1) combine with various groundwater and geochemistry issues to enable the understanding of the performance issues of water contacting the backfill (B.3), disturbed zone transport (B.9), far-field transport (B.10), and pre-waste-emplacement groundwater travel time (B.11). Table C-3, in combination with Table C-1, also shows how each issue is based on the performance objectives of 10 CFR 60.

Developing the specific issues involved judgment as to which conditions and processes are considered to be significant to performance issues. Therefore, every possible condition and process is not listed, rather only those judged by the NRC staff as potentially significant. Issue identification is based on technical reviews of various BWIP-related documents, site visits, workshops, and research activities conducted by NRC, DOE, and other organizations.

Judgment is a factor in breaking down the specific issues to various levels of detail. Different levels of breakdown reflect the degree of emphasis on a particular program area at this stage in site characterization. For example, more detail is developed for issues related to the site rather than repository design because site investigations provide input to repository design and because many site investigations take months or years to conduct and therefore require long lead times for planning.

4 ISSUE RATINGS

The NRC site issues are used as a framework for an analysis by the NRC staff of the BWIP site characterization program. This section summarizes this analysis by presenting ratings for each site issue.

All issue ratings are supported by site issue analyses (SIAs), which are working papers developed during the early stages of the SCR analysis. There are no SIAs for the performance issues, because all the SIAs for supporting specific issues collectively make up an analysis of each performance issue. All of the SIAs are compiled into one single document and copies are located in the NRC Public Document Room. Issue ratings are further supported by the chapters and technical appendices in the SCA. This supporting material is referenced in Table C-4.

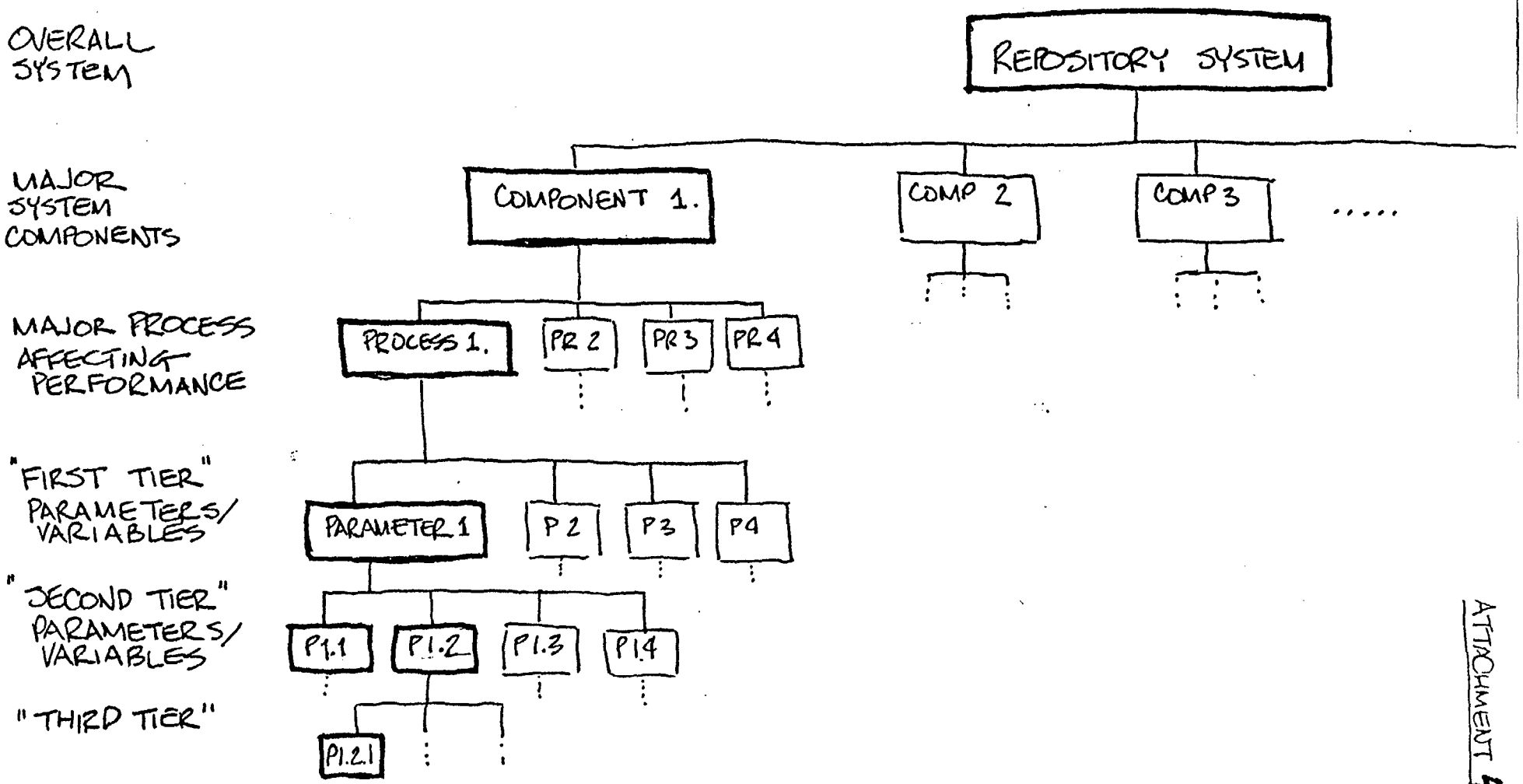
Issue ratings are given for the following four categories: (1) importance to repository performance and suitability; (2) ease of resolution; (3) current level of resolution, based on SCR contents and information gained during technical interactions with DOE and DOE contractors; and (4) likely level of resolution with proposed site characterization plans described in the SCR. The ratings represent a consensus judgment made by the respective technical review team members. Issue ratings, rating classes, and symbols are shown in Table C-5. An indeterminate rating is assigned when not enough information is available in the SCR and referenced documents for the staff to make a judgment.

5 CORRELATION OF NRC AND DOE ISSUES AND WORK ELEMENTS

The DOE site characterization plans are organized and presented using their issue/work element structure. Tables C-5 and C-6 list the numbered DOE issues and work elements.

The analysis of the site characterization program for each NRC issue included identifying and evaluating those DOE issues and work elements that correspond partially or completely to the NRC issue. Table C-2 shows this correlation of DOE issue and work element numbers to the NRC issues. Tables C-2, C-5, and C-6 together are intended to be a cross-referencing tool for relating NRC's analysis in the SCA chapters and SIAs to DOE's plans in the SCR.

ATTACHMENT 4



ATTACHMENT 4.

SCHEMATIC DIAGRAM
OF LICENSING INFORMATION NEEDS
"LOGIC-TREE"

ATTACHMENT 4.

SCHEMATIC DIAGRAM
"LOGIC-TREE"

FIGURE - FOOTNOTES

1. At each level in the logic-tree, system components, variables and parameters are linked by constitutive equation and conceptual models.

2. Completion of the logic-tree would occur through a process similar to that utilized in Appendix C (see attachement).

3. In the logic-tree there is repetition of some parameters as they can be important factors in controlling the process which affect performance of more than one system component.

2. The actions taken thus far by the NRC Staff in its SEP assessment of the La Crosse plant are acceptable.

3. The ACRS will defer its review of the FTOL for the La Crosse plant until the NRC Staff has completed its actions on the remaining SEP topics and the Unresolved Safety Issues and TMI Action Plan items.

Mr. Harold Etherington did not participate in Committee consideration of this matter.

Sincerely,

Jesse C. Ebersole

Jesse C. Ebersole
Acting Chairman

References:

1. U. S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, "Integrated Plant Safety Assessment Systematic Evaluation Program, La Crosse Boiling Water Reactor," Draft Report, NUREG-0827, dated April 1983.
2. U. S. Nuclear Regulatory Commission, Safety Evaluation Reports, La Crosse Boiling Water Reactor, Volumes 1-3, received April 15, 1983.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

May 17, 1983

Honorable Nunzio J. Palladino
Chairman
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Dr. Palladino:

SUBJECT: ACRS REPORT ON THE SYSTEMATIC EVALUATION PROGRAM REVIEW OF THE HADDAM NECK PLANT

During its 277th meeting, May 12-14, 1983, the Advisory Committee on Reactor Safeguards reviewed the results of Phase II of the Systematic Evaluation Program (SEP) as it has been applied to the Haddam Neck Plant. These matters were discussed also during a Subcommittee meeting in Washington, D.C. on April 7, 1983. During our review, we had the benefit of discussions with representatives of the Connecticut Yankee Atomic Power Company (Licensee) and the NRC Staff. We also had the benefit of the documents referenced.

The Haddam Neck Plant is the second plant in Group 2 of the SEP to be reviewed; our review of the Yankee Plant was reported in our letter dated April 19, 1983. The Haddam Neck Plant has been in commercial operation since 1968 and is the fourth oldest licensed power plant still operating. It has produced more kilowatt-hours of electricity than any other nuclear power plant in the world. The Haddam Neck Plant, like the Yankee Plant, differs from most of the other plants in the SEP in that it received a Full-Term Operating License in 1974. At an electrical capacity of 575 MWe, it is the largest plant in Group 2.

In our report dated May 11, 1982 on the SEP evaluation of the Palisades Plant, we commented on the objectives of the SEP and the extent to which they had been achieved. Our review of the SEP in relation to the Haddam Neck Plant has led to no changes in our previous findings regarding the extent to which the objectives of the SEP have been achieved and the manner in which the NRC Staff has conducted its review and assessment.

Of the 137 topics to be addressed in Phase II of the SEP, 24 were not applicable to the Haddam Neck Plant and 23 were deleted because they were being reviewed generically under either the Unresolved Safety Issues Program or the Three Mile Island Action Plan. Of the 90 topics addressed in the NRC Staff's review, 46 were found to meet current NRC criteria or to be acceptable on another defined basis. We have reviewed the assessments and conclusions of the NRC Staff relating to these topics and have found them appropriate.

The 44 remaining topics involved 79 issues relating to areas in which the Haddam Neck Plant did not meet current criteria. These issues were addressed by the Integrated Plant Safety Assessment and various resolutions have been proposed.

For 17 of the 79 issues included in the Integrated Assessment, the NRC Staff concluded that no backfit is required. We concur.

For 19 of the remaining issues, changes to the Technical Specifications or procedures were recommended by the NRC Staff and agreed to by the Licensee.

For the 10 remaining issues for which the assessment has been completed, the Licensee has proposed hardware backfits for their resolution, and the NRC Staff has found these proposals acceptable.

As has been the case for the other plants in the SEP, the Integrated Assessment has not been completed for a number of the issues for which the Licensee has agreed to provide the results of studies, analyses, and evaluations needed by the NRC Staff for its assessments and decisions. All of these issues are of such a nature that hardware backfits may be required for their resolution. The resolution of these issues will be addressed by the NRC Staff in a supplemental report.

Many of the issues still being evaluated by the Licensee relate to the effects of extreme environmental phenomena such as earthquakes, floods, and tornadoes, since the Haddam Neck Plant was not designed to resist these phenomena at the levels that would be required by current criteria.

Use was made of a limited Probabilistic Risk Assessment (PRA) in connection with the NRC Staff's evaluations. Since a plant-specific PRA was not available for the Haddam Neck Plant, the techniques used were similar to those used in similar circumstances for other plants in the SEP. As in those other cases, we believe that the NRC Staff's use of PRA was appropriate and that suitable use was made of the results.

Our conclusions regarding the SEP review of the Haddam Neck Plant are as follows:

1. The SEP has been conducted in such a manner that the stated objectives have been achieved for the most part for the Haddam Neck Plant.

2. The actions taken thus far by the NRC Staff in its SEP assessment of the Haddam Neck Plant are acceptable.

3. Several issues relating to protection against extreme external events remain to be resolved. We have been informed of the bases for the resolution of these issues but have not yet reviewed them in detail. At this time, we are satisfied with the SEP review of the Haddam Neck Plant. We expect to review further the design bases for protection against external events, and we wish to review the resolution of the remaining issues when the supplemental report is available.

Sincerely,

Jesse C. Ebersole

Jesse C. Ebersole
Acting Chairman

References:

1. U. S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, "Integrated Plant Safety Assessment Systematic Evaluation Program, Haddam Neck Plant," Draft Report, NUREG-0826, dated March 1983.
2. U. S. Nuclear Regulatory Commission, Safety Evaluation Reports, Haddam Neck Plant, Volumes 1-3, received March 18, 1983.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

May 17, 1983

Mr. William J. Dircks
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Dircks:

SUBJECT: ACRS SUBCOMMITTEE REPORT ON CONTROL ROOM HABITABILITY

On April 28, 1983, the ACRS Subcommittee on Reactor Radiological Effects met with the NRC Staff for follow-up discussions on the subject of control room habitability. Serving as a basis for these discussions was the ACRS letter to Chairman Palladino of August 18, 1982, and your responses of September 17, 1982, and January 31, 1983.

On the basis of these discussions, the Subcommittee has summarized its comments and a copy is enclosed for your information.

We look forward to continuing discussions with the NRC Staff on this matter.

Sincerely yours,

Jesse C. Ebersole

Jesse C. Ebersole
Acting Chairman

Enclosure:
"Response to NRC Staff Comments on Control Room Habitability," Prepared by Subcommittee on Reactor Radiological Effects, ACRS, 4/30/83

Response to NRC Staff Comments on
Control Room Habitability

Prepared by
Subcommittee on Reactor Radiological Effects
Advisory Committee on Reactor Safeguards
April 30, 1983

This report represents a follow-up to the ACRS letter of August 18, 1982 on the subject of control room habitability. On the basis of the responses of the NRC Staff and discussions held on April 28, 1983, the Subcommittee continues to be concerned about this matter. If a control room becomes uninhabitable, the NRC Staff assumes that the operators can retreat to the remote shutdown panel and manage the nuclear power plant from there. Since the shutdown of a nuclear power plant on an emergency basis is a serious matter, we believe the preferred option is to increase the habitability of the main control room to permit the operators to remain at their normal posts. To this extent, we believe that improvements in control room habitability are justified for safety reasons.

General Comments

1. The Subcommittee continues to be concerned that the reviews and evaluations by the NRC Staff of problems associated with control room habitability are not centralized. No single NRC group has the responsibility for coordination and integration of such reviews and communications among the groups involved appear to need improvement. We recommend that one of the groups involved be assigned the administrative and technical responsibilities for coordinating all reviews and evaluations on this subject.

2. The NRC Staff members involved appear to be too ready to accept the responses of applicants and licensees on these matters, rather than assuring themselves on an independent basis that conditions are acceptable. Some of the models used by the licensees (for example, those for estimating the rate of temperature rise in a control room following the loss of the air cooling system) appear to be supported by insufficient experimental data. The Subcommittee suggests a more aggressive approach by the NRC Staff in critically reviewing potential problems related to control room habitability.

3. The Subcommittee also recommends that the NRC Staff be more aggressive in seeking information on equipment failures that might affect control room habitability. The NRC Regional Office staffs, for example, may

be able to obtain data of interest to the NRC Headquarters regulatory staff. In this regard, efforts are also needed to assure that failures in nuclear power plant safety-related heating, ventilating and air conditioning (HVAC) systems are included in the Nuclear Plant Reliability Data System (NPRDS) since the Subcommittee understands that they will not be included in the proposed revisions of the NRC LER system. The reasons that INPO did not agree to provide to the NRC Staff data on HVAC systems developed by consultants to nuclear power plant utilities also need to be clarified.

Specific Comments

1. The formal response by the NRC Staff to our recommendations for a generic diffusion study to assist in determining the optimum location of alternate air intakes for control room systems was negative, on the basis that close-in structures and terrain features would invalidate their diffusion models. Yet, at the Subcommittee meeting, they acknowledged that, in fact, a downwash analysis would be applicable to this kind of assessment. We agree that such an analysis is generically applicable because of similarities among control room air systems in standardized nuclear power plants. We therefore recommend that the NRC Staff reevaluate this subject on the basis of the discussions during the Subcommittee meeting.

2. Conditions for human comfort within a control room are based on a maximum acceptable temperature of 120°F. When humidity from human perspiration is added to a room under these conditions, possibly combined with a low air exchange rate, the situation could readily become intolerable. Also to be considered is the possibility that the charcoal preheaters in the air recirculating system may contribute an added heat load. The Subcommittee believes that these factors should be given careful consideration and that the criterion for temperature limits in a control room should be revised, if necessary.

3. The Subcommittee believes that the NRC Staff needs to develop a protocol for testing control room HVAC systems. Criteria for acceptance should be based on conditions that permit continuing equipment functionability and human comfort during prolonged emergency situations. All ports, including dampers, ducts, etc., should be tested simultaneously as a complete system under both positive and negative pressures. Particular attention should be given to assure that sections of such systems that are under negative pressure will not bring in contaminants, which later can gain access to the control room. Possible damage to vital equipment due to pressure surges and disruption of HVAC systems should also be evaluated.

4. The Subcommittee believes that the quality assurance aspects of HEPA filter manufacturing, installation and testing need to be given more attention by the NRC Staff. Included in Regulatory Guide 1.52 are references to ANSI N-509 and N-510 which, in turn, reference the applicable military specifications. The Subcommittee was told, however, by a representative of one of the filter manufacturers, that some nuclear power plant operators are purchasing HEPA filters that do not meet these specifications. This information should be transmitted to the appropriate NRC Offices (e.g., IE) for further investigation, and corrective action should be taken, if needed. The question of whether Quality Product Listing (QPL) certification is an essential part of the military specifications was not clear. The NRC should contact appropriate groups such as the Edgewood Arsenal and the ASME Committee on Nuclear Air and Gas Treatment for clarification of this matter. Relevant information and decisions, as appropriate, should be included in the revision of Regulatory Guide 1.52.

5. The NRC Staff indicated that fire dampers are intended to prevent the spread of a fire but are not designed or certified to hold back the accompanying smoke or potentially toxic gases. If this is true, the Subcommittee believes that data need to be obtained on allowable leak rates for such dampers and whether the design leak rate is achieved in practice. If leak rates are as high as was indicated by the NRC Staff, are there situations and/or systems in which auxiliary dampers should be installed to provide supporting seals? Simply to state that fire dampers "have been proven in industrial operations" is not adequate. Recent reviews of LERs indicate that damper failures frequently occur in nuclear installations.

6. The reasons given by the Staff for rejecting our earlier recommendation that consideration be given to increasing the depth of charcoal beds in nuclear adsorption systems are not convincing. Two factors appear relevant to this matter. First, deeper beds are just as effective for high acute exposures as they are for chronic low exposures (up to the capacity of the charcoal to retain the contaminants). As a result, deeper beds are better able than thinner beds to handle high acute contaminant concentrations. Second, the U.S. philosophy that the control room be sealed rather than be designed to cope with high air intake concentrations will be fully effective only for those plants having auxiliary compressed air tanks for pressurizing the room; others must take in outside air to maintain pressurization.

7. The Subcommittee noted a range of additional potential problems that appear to need evaluation in terms of control room habitability. These include:

a. The impact of the loss of all AC power, of auxiliary services to the chiller systems, of service air, and of component cooling water;

b. Careful evaluation of all potential sources of heat input in assessing possible temperature increases in degraded operating modes;

c. The potential need for monitoring oxygen concentrations and steam intrusion;

d. Whether the current detection limits for contaminants in the intake air to control rooms are sufficient to protect personnel.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

May 16, 1983

Honorable Nunzio J. Palladino
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Dr. Palladino:

SUBJECT: ACRS REPORT ON THE PROPOSED FINAL RULES ON IMMEDIATE NOTIFICATION REQUIREMENTS (10 CFR 50.72) AND LICENSEE EVENT REPORTING (10 CFR 50.73)

During its 277th meeting, May 12-14, 1983, the Advisory Committee on Reactor Safeguards considered the proposed final rules on Immediate Notification Requirements and the Licensee Event Reporting (LER) system. A Subcommittee meeting to discuss the rules was held in Washington, D.C. on April 6, 1983. The Committee reported on the LER rulemaking prior to publication of this rule for public comment in a report to Commissioner Ahearne on March 9, 1982.

The proposed rule on Immediate Notification Requirements will reduce the number of reports having little or no safety significance. The rule will also allow somewhat more flexibility in reporting times and reflects improved coordination with other reporting requirements in the regulations.

The proposed LER rule also reduces the number of reports required and improves coordination with other reporting requirements. Reporting of events that have the potential for safety significance will be more complete and useful to analysts of operational data.

We believe that implementation of these rules would represent a substantial improvement over current reporting requirements.

As a complement to the new LER system, it is essential to have an effective Nuclear Plant Reliability Data System (NPRDS) to collect information related to the failure rates of safety-related components used in nuclear power plants. Without an effective NPRDS, the overall reporting scheme of the industry would be seriously deficient. NPRDS is being administered by the Institute of Nuclear Power Operations, and the NRC Staff is periodically examining its effectiveness. If, after a reasonable amount of time for implementation, the NRC Staff determines that NPRDS is not acceptable, remedial measures such as additional rulemaking to codify the NPRDS would be appropriate. We believe that the effort needed to make NPRDS a success represents a challenge to the industry. We wish to be kept informed of the progress toward implementing NPRDS and informed by the NRC Staff when both the LER system and NPRDS are working in concert.

Mr. Carlyle Michelson did not participate in Committee consideration of this matter.

Sincerely,

Jesse C. Ebersole
Acting Chairman

References:

1. Memo from R. DeYoung, Office of Inspection and Enforcement, NRC, to R. Fraley, ACRS, dated March 25, 1983, Subject: Immediate Notification Requirements Rulemaking (10 CFR 50.72) [includes proposed Federal Register Notice for the final Immediate Notification rule (50.72)].
2. Memo from C. J. Heltemes, Office for Analysis and Evaluation of Operational Data, NRC, to R. Fraley, ACRS, dated March 21, 1983, Subject: Licensee Event Report (LER) Rulemaking (10 CFR 50.73) [includes proposed Federal Register Notice for the final LER rule (50.73)].
3. Feasibility Study on the Acquisition of Licensee Event Data, dated October 25, 1982, Brookhaven National Laboratory, BNL/NUREG-51609, NUREG/CR-3026.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

May 16, 1983

Mr. William J. Dircks
Executive Director for Operations
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Dircks:

Subject: ACRS ACTION ON PROPOSED REGULATORY GUIDE ON INSTRUMENT SENSING LINES (TASK NO. IC 126-5)

During its 277th meeting, May 12-14, 1983, the Advisory Committee on Reactor Safeguards concurred in the regulatory position of the proposed Regulatory Guide on Instrument Sensing Lines (Task No. IC 126-5), dated November 8, 1982.

We note that the provisions of this Guide and the Standard referenced in it are not to be backfitted to those nuclear power plants now operating or under construction.

We are concerned that there may be instrument lines in operating plants in which inappropriate combinations of transducers are connected to common instrument lines. We recommend that the operating plants be examined to verify that failure of such lines would not cause unacceptable consequences.

Sincerely,

Jesse C. Ebersole
Acting Chairman

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

May 16, 1983

Honorable Nunzio J. Palladino
Chairman
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Dr. Palladino:

Subject: ACRS REPORT ON REGIONALIZATION

During its 274th, 275th, 276th, and 277th meetings, February 10-12, 1983, March 10-12, 1983, April 14-16, 1983, and May 12-14, 1983, respectively, the Advisory Committee on Reactor Safeguards has continued to study the plan for regionalization of certain NRC operations. As a result of the discussion during the 276th meeting, we sent you a letter on April 19, 1983 expressing concern about the potential negative impact of regionalization on reactor safety, but did not, at that time, spell out the exact nature of our concerns. For this reason, we thought it worthwhile to send you a clarification in the hope that that may help to focus the discussion. Our major concerns are:

1. Dilution of technical talent: We are concerned about whether it is possible to form six adequately staffed multidisciplinary organizations (Headquarters and the Regional Offices) with the current NRC staffing and resource limitations.

2. Fragmentation of multidisciplinary interaction: The regulation of the nuclear industry calls for the consideration of complex systems and their integration, which requires the application of many diverse disciplines. Interactions among the needed disciplines are essential, and are facilitated when the people involved have easy access to each other. We are concerned that regionalization will make this access more difficult.

3. Division and confusion of authority between NRC Headquarters and the Regional Offices: The potential for confusion as to where the ultimate authority of the Staff lies (with the Regional Administrators or with Headquarters) will be increased by regionalization. We believe that a structured appeal process will be needed with provisions for protection against possible retaliation by Regional authorities who might be sensitive to appeals over their heads.

4. Lack of uniformity among the Regions: As decisions are made in the Regions, it will be unavoidable that differences in interpretation and implementation of regulations will occur. This lack of uniformity could have significant safety implications.

5. Maintenance of lines of communication: The benefits of shared operating experience will be lost unless effective communication channels are provided among the Regional Offices, and between the Regions and NRC Headquarters. There are already communication problems among the separate offices at NRC Headquarters, and these will certainly not be relieved by regionalization.

6. Decisions on which issues have significance beyond a specific Region: Although it is proposed that issues with generic implications will be handled at NRC Headquarters, the decisions on which issues fall into this category will be made in the Regional Offices. We are concerned that the relatively small technical staffs at the Regional Offices will not have sufficient experience or expertise to make appropriate decisions on these issues.

In addition, we might note that the ad hoc National Academy of Sciences' review of the Federal Aviation Administration (FAA) in the aftermath of the Chicago DC-10 accident (aviation's TMI) strongly criticized the regionalization of FAA, for many of the reasons we have mentioned here. While there are differences in the two cases, the many similarities make the Academy group's conclusions difficult to ignore.

Sincerely,

Jesse C. Ebersole
Acting Chairman

ATTACHMENT 5

ATTACHMENT 5.

(2) After permanent closure

§60.112, limiting releases of radioactive materials to the accessible environment after permanent closure to those permitted by the EPA standard (proposed 40 CFR 191).

§60.113(a)(1)(ii)(A), requiring a minimum waste package containment time.

§60.113(a)(1)(ii)(B), limiting the radionuclide release rate from the engineered barrier system.

§60.113(a)(2), addressing minimum pre-emplacement groundwater travel time from the disturbed zone to the accessible environment.

In addition to the above numerical performance objectives, performance assessment contributes to many of the other assessments that 10 CFR 60 requires. For example, the purpose of assessing favorable and potential adverse geologic conditions (§60.122) is to determine whether they support or interfere with the ability of the geologic repository to comply with the performance objectives; performance assessment is an essential step in determining the relationship between the performance objectives and the favorable and potentially adverse conditions.

9.1.3 Approach to Performance Assessment

The central question underlying the NRC staff review of the DOE proposed site characterization program is: "Will it produce the information required to conduct a licensing assessment?" The review of the SCR, therefore, started with and revolves around the analysis of what the regulation requires that the licensing assessment includes. The licensing assessment includes both (1) the quantitative assessments that will address the numerical performance objectives and (2) the semi-quantitative and qualitative assessments that will be made to determine compliance with the nonnumerical requirements and criteria and to provide input to the quantitative assessments.

Performance assessment requires the identification of credible scenarios; determination of the likelihood of those scenarios; development of conceptual models that describe the scenarios; formulation of numerical models that are consistent with the conceptual models; and incorporation of data and associated uncertainties into the numerical models. These activities interact with the repository development process in that the models will suggest information needs to be filled by site characterization or by engineering development. Conversely, the development process is likely to identify improvements in the conceptual models. During the formal licensing process, performance assessment will include assessment of the consequences of the scenarios and the uncertainties associated with those assessments, and, finally, comparison of the results with numerical performance objectives.

The performance assessment steps described above and their interaction with the site characterization program can be seen in the simplified logic diagram which appears in Figure 9-1. As shown in this figure, the initial step in site characterization is the establishment of the present level of understanding about the site, followed by identification of the performance issues which eventually must be addressed to determine whether the site and the engineered system will

comply with NRC regulations. These issues must be the basis for the development of specific assessment methods, including both conceptual and mathematical models. The models, and sensitivity studies based on them, are the basis for determining the information needs that must be addressed during site characterization. Given the complexity of the technical issues associated with a geologic repository, it is essential that sensitivity studies begin early to determine the most important factors to repository performance. Further, sensitivity studies should be conducted at several levels to determine what are essential information needs. As identified by the staff in the SCA chapters, sensitivity studies of the overall repository system performance as well as components and subsystems, such as the waste package or engineered barriers, are needed to assure that limited resources are directed to the most important parameters. The simplified system breakdown in Figure 9-2 identifies some technical areas in which sensitivity studies can be appropriate.

It is also necessary to establish initial component requirements in parallel with the development of assessment methods. The nature of many of these requirements can be inferred directly from the performance issues, and, once they have been established, they make an essential contribution to identifying information needs. Acceptable levels of uncertainty are established here, and directly affect the amount and quality of data needed.

Once information needs have been identified, the establishment of test plans and procedures follows directly, and forms the basis for generating data and determining the uncertainties associated with them. These data and uncertainties can then be used to upgrade the sensitivity studies and thereby further develop the assessment methods and refine the component requirements. This process by its nature must be an evolving, iterative one. It must start with the use of substantial judgment and relatively simple models. As the program proceeds and more data are gathered, the process will become more refined.

Finally, during the formal licensing process, the data and uncertainties, as treated by the assessment methods, form a basis for NRC to reach findings as to whether the regulatory criteria have been met.

Although all of the above activities are essential for conducting performance assessment, activities involving development of conceptual models and generation of data are addressed in other chapters of this Draft SCA. This chapter is concerned with approaches to performance assessment and the development and evaluation of numerical models and computer codes and their use in assessing geologic repository systems and components relative to the numerical criteria of 10 CFR 60.

Determinations of compliance or noncompliance with the numerical criteria will be consistent with that portion of 10 CFR 60, which states

> Proof of the future performance of the engineered barrier system and the geologic setting over time periods of many thousands of years is not to be had in the ordinary sense of the word. For such long-term objectives and criteria, what is required is reasonable assurance, making allowances for the time period, hazards, and uncertainties involved, that the outcome will be in conformance with these objectives and criteria.

That is, the staff expects that a classic probabilistic risk analysis (based on rigorous probablity determinations) of the repository may be neither possible nor necessary, and that determinations of compliance with the numerical criteria may depend in part on expert judgment for items such as conceptual models, scenarios, scenario probabilities, estimated parameter values, boundary locations, and uncertainties. For example, it is expected that numerical models will be used to estimate the consequences of specific scenarios, and will take into account the uncertainties associated with the behavior of the repository within those scenarios. However, it is expected that estimations of the probabilities of the occurrence of the scenarios, and the uncertainties associated with the data pertaining to the scenarios, will be based in part on expert judgment.

9.1.4 Definitions

Accessible environment. (1) the atmosphere, (2) land surfaces, (3) surface water, (4) oceans, and (5) the portion of the lithosphere that is outside the controlled area. The overall system performance for the geologic repository is calculated at this boundary (§60.2).

Computer code. A set of computer instructions for performing the operations specified in a numerical model.

Consequence analysis. A method by which the consequences of an event is calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

Controlled area. A surface location, to be marked by suitable monuments extending horizontally no more than 10 km in any direction from the underground facility, and the underlying subsurface, which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure (§60.2).

Disturbed zone. That portion of the controlled area whose physical or chemical properties have changed as a result of underground facility construction or from heat generated by the emplaced radioactive wastes such that the resultant change of properties may have a significant effect on the performance of the geologic repository. The minimum groundwater travel time is calculated between this boundary and the accessible environment (§60.133(a)(2)).

Engineered barrier system. The waste packages and the underground facility. The maximum radionuclide release rate is measured at this boundary (§60.113(a)(1)(ii)(B)).

Finding. A determination of compliance or noncompliance with a specific requirement. A finding addressing a numerical performance objective will be reached after the following are weighed: the results of a reliability analysis and the laboratory and field tests upon which it is based, expert opinion, and empirical studies.

Licensing assessment. An assessment of whether a license application complies with all of the requirements that it purports to meet. For this program it is the sum of the individual findings for each of the requirements of 10 CFR 60.

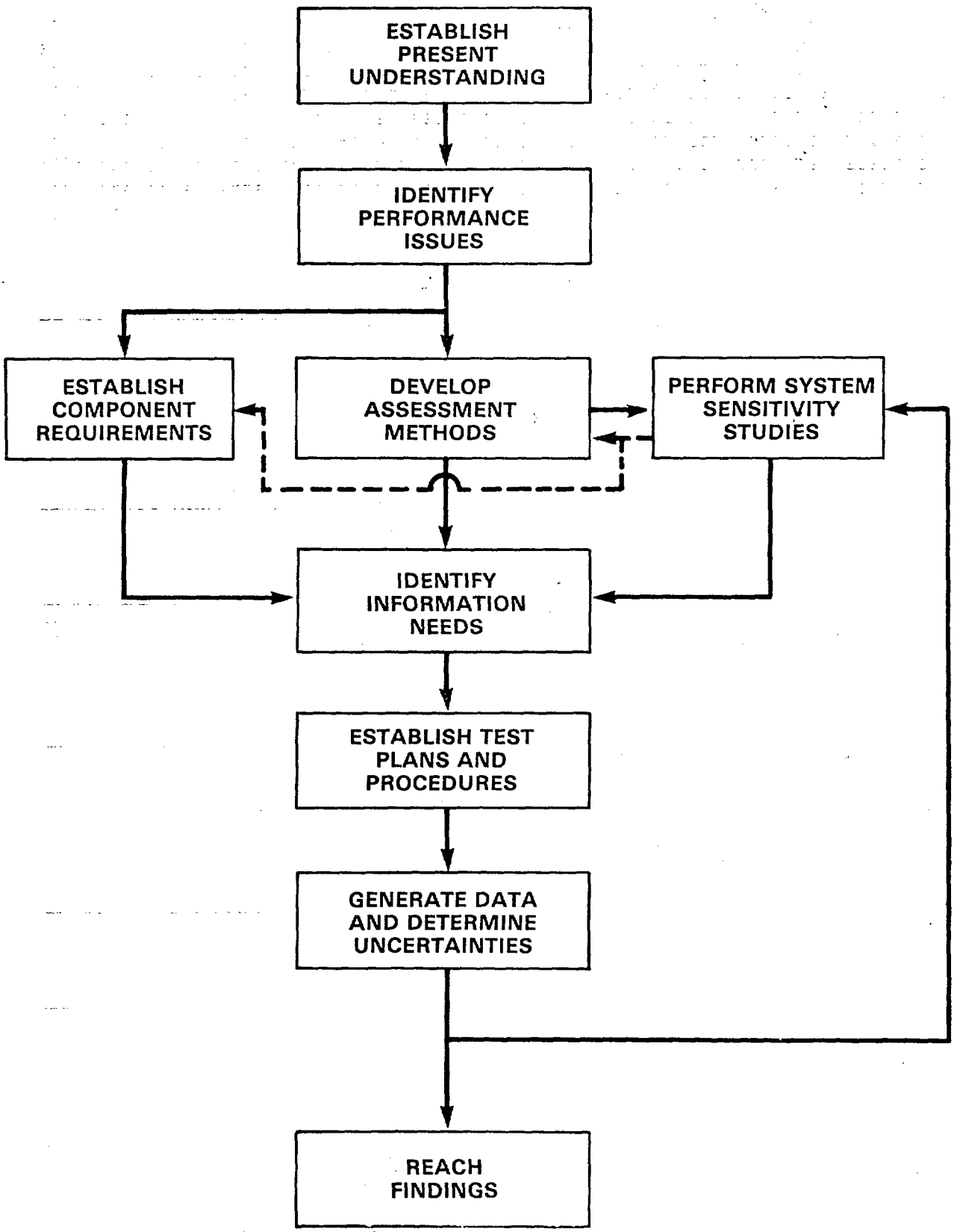


Figure 9.1 Site characterization - program logic

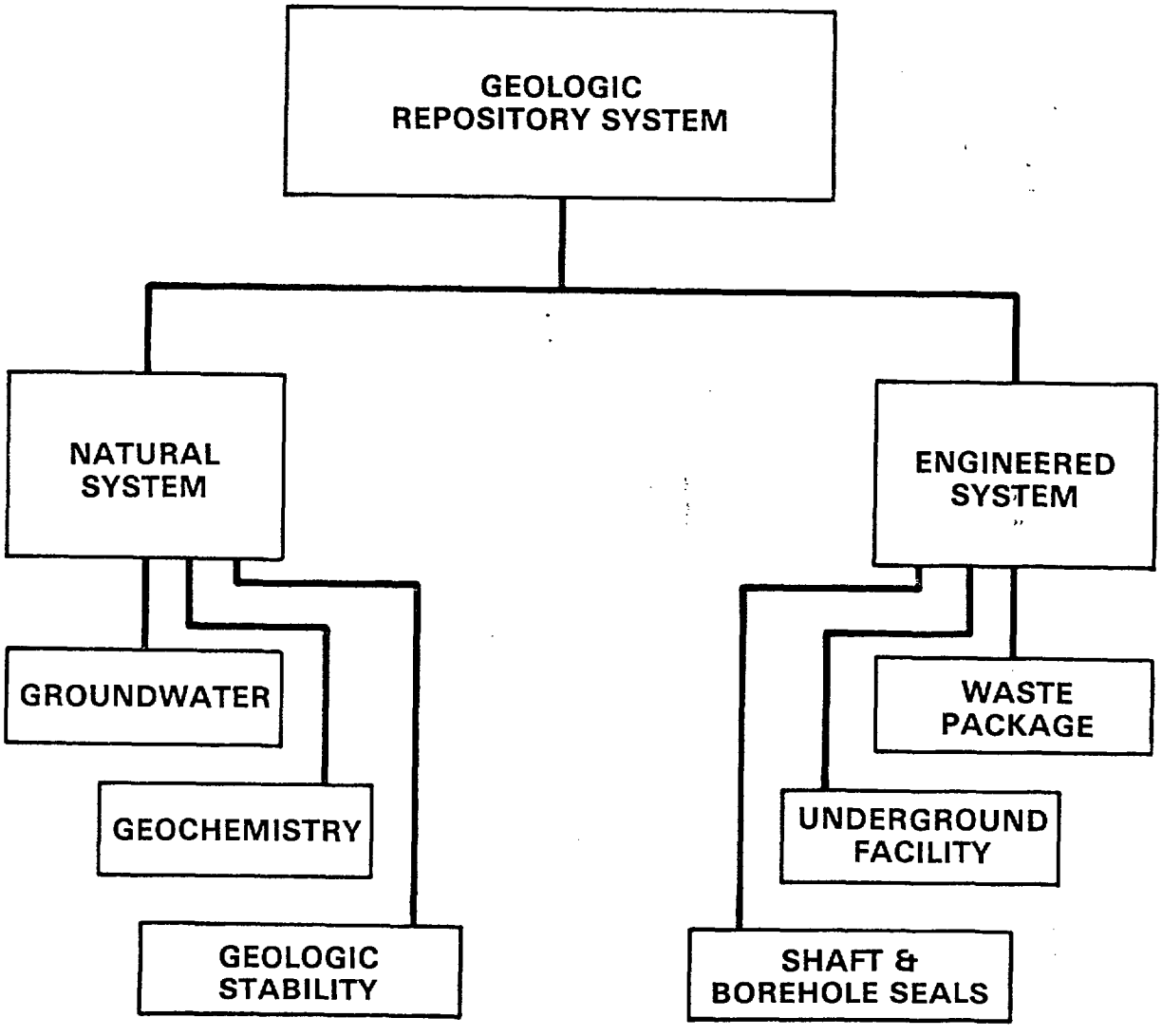


Figure 9.2 System breakdown

ATTACHMENT 6

ATTACHMENT 6.

preliminary evaluation of the DOE response, the staff finds that there are no apparent adverse safety-related effects that might be impacted by the initial phase of shaft construction (drilling of 365-cm-diameter hole from surface to the top ~~of the basalt formation).~~ Resolution of outstanding questions at an early time is essential. (See pages 6-6 and 6-7.)

(8) Although the layout of the excavation for in situ tests appears reasonable, specific information on some in situ test plans should be included in the SCR. Some in situ tests require long planning, and some testing is to start as ~~early as March 1984. The staff~~ must review these plans (for example, specific details on measurement of in situ stress and rock mass strength) to ensure that the quality and quantity of data available at the license application stage are likely to be sufficient so the NRC staff can make the required findings. In developing the specific plans for this testing, careful consideration must be given to the scale of excavations and testing to evaluate (1) the potential effects of rock mass features exhibited in basalts and (2) the effects that heat will have on groundwater and rock conditions around waste packages (see pages 6-9 through 6-11).

(9) The SCR does not adequately address retrievability of waste. The proposed concept of emplacement of waste in long (66 m), horizontal boreholes between drifts is unproven. As mentioned in the SCR, new equipment must be developed and tested to ensure that the retrievability option is achievable with this emplacement mode. These activities require long planning, and the results can have significant impact on repository design. Some testing will have to be performed before the license application to provide reasonable assurance that the requirements of the retrieval option can be met. General plans to demonstrate feasibility of emplacing packing around waste packages and subsequently retrieving such packages is mentioned; however, the details of such testing are not presented (see pages 6-8 and 6-9).

(10) Selection of candidate sealing materials for use in decommissioning is not planned until 1984. This is late in the program and will allow only limited time for the test program before the license application. Trade-off studies should be started as soon as possible (see pages 6-5 and 6-6).

(11) The current conceptual design is based on horizontal waste emplacement. This arrangement does not take advantage of the waste isolation properties of emplacement room backfill. The SCR does not discuss the trade-offs considered when the horizontal emplacement mode was selected, particularly the lessening of potential isolation benefits from emplacement room backfill (see pages 6-4 and 6-5).

Waste Form and Package

(12) Although the SCR identifies broad performance objectives for the waste package and other components of the engineered barrier system, it does not identify the specific performance requirements needed for system components to provide reasonable assurance that the broader performance objectives will be met. Quantitative levels of performance, expressed in terms of reliability, are not identified. Early development of such

requirements is needed to determine specific testing needs, because testing needs are dependent on the reliability required. Although final reliability requirements need not be set at the present time, interim requirements should be established. A plan should be developed to show how these will be applied to guide the testing program (see pages 7-2 and 7-3).

(13) The staff is concerned that readily available information on pitting corrosion of materials like those proposed for the waste container in the conceptual design has not been fully considered in the conceptual design. While the general design concept appears to be reasonable for the BWIP, thickness of the waste container appears inadequate to provide reasonable assurance of containment as required by 10 CFR 60 (see pages 7-3 through 7-5).

(14) The NRC staff considers that the SCR generally discusses the kind of information needed for the waste package and the kinds of tests to be run to obtain it. However, the SCR does not provide the strategy to be employed in selecting tests to cover the range of possible repository conditions or specific information on the tests to be conducted. Neither does the SCR identify a specific plan to produce such strategy. Therefore, the staff is not able to determine whether the test program will develop the needed information for licensing (see pages 7-3 through 7-7).

(15) The SCR suggests that waste-containing borosilicate glass will degrade if it is attacked by hydrothermal solutions entering a failed waste container. However, no specific plans are presented for testing the performance of borosilicate glass under the expected range of conditions for the BWIP waste package. In the absence of such data, the staff is apt to have unresolved questions at licensing. Such plans should be a part of the BWIP waste package program (see pages 7-8 and 7-9).

Performance Assessment

(16) A clear and consistent approach and framework for performance assessment are not adequately described or related to licensing assessment. These should be provided very early in the site characterization program. Further, the iterative process between data collection and numerical modeling should be described in more detail, and plans for its use should be developed. This process can be very valuable in determining quantitative performance requirements, thereby determining what kind of and how much testing will be needed (see pages 9-9 through 9-11).

(17) It is essential that all computer analyses important to site evaluation be thoroughly documented so that they can be independently examined by the NRC staff. Some of the computer codes and input data used in the SCR analyses are not documented in a way that permits an independent replication of results. Unless the documentation of a code and input data is complete and available to the NRC staff, the staff must consider any results that depend on these items to be inconclusive (see pages 9-14 and 9-15).

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

May 17, 1983

Honorable Nunzio J. Palladino
Chairman
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Dr. Palladino:

SUBJECT: ACRS REPORT ON THE SYSTEMATIC EVALUATION PROGRAM REVIEW OF THE LA CROSSE BOILING WATER REACTOR

During its 277th meeting, May 12-14, 1983, the Advisory Committee on Reactor Safeguards reviewed the results of Phase II of the Systematic Evaluation Program (SEP) as it has been applied to the La Crosse Boiling Water Reactor. These matters were also discussed during a Subcommittee meeting in Washington, D. C. on May 6, 1983. During our review, we had the benefit of discussions with representatives of the Dairyland Power Cooperative (Licensee) and the NRC Staff. We also had the benefit of the documents referenced.

The La Crosse plant is the third in Group 2 of the SEP to be reviewed; our review of the Yankee plant was reported in our letter dated April 19, 1983, and our review of the Haddam Neck plant is reported in our letter dated May 17, 1983. The La Crosse plant is unique in several respects. It includes a boiling water reactor, designed and built by the Allis-Chalmers Company as part of the Atomic Energy Commission's Second Round Demonstration Program and was subsequently turned over to the current Licensee. It has been in commercial operation since 1969 but, like several other plants in the SEP, has not yet been issued a Full-Term Operating License (FTOL). Of particular interest is the fact that, with an electrical power output of 50 MWe, it is the smallest commercial power reactor in operation in the United States.

In our report dated May 11, 1982 on the SEP evaluation of the Palisades plant, we commented on the objectives of the SEP and the extent to which they had been achieved. Our review of the SEP in relation to the La Crosse plant has led to no changes in our previous findings regarding the extent to which the objectives of the SEP have been achieved and the manner in which the NRC Staff has conducted its review and assessment.

Of the 137 topics to be addressed in Phase II of the SEP, 36 were not applicable to the La Crosse plant and 18 were deleted because they were being reviewed generically under either the Unresolved Safety Issues Program or the Three Mile Island Action Plan. Of the 83 topics addressed

in the NRC Staff's review, 52 were found to meet current NRC criteria or to be acceptable on another defined basis. We have reviewed the assessments and conclusions of the NRC Staff relating to these topics and have found them appropriate.

The 31 remaining topics involved 70 issues relating to areas in which the La Crosse plant did not meet current criteria. These issues were addressed by the Integrated Plant Safety Assessment and various resolutions have been proposed.

For 27 of the 70 issues included in the Integrated Assessment, the NRC Staff concluded that no backfit is required. We concur.

For 21 of the remaining issues, changes to the Technical Specifications or procedures were recommended by the NRC Staff and agreed to by the Licensee.

For the 6 remaining issues for which the assessment has been completed, the Licensee has proposed hardware backfits for their resolution and the NRC Staff has found these proposals acceptable.

As has been the case for the other plants in the SEP, the Integrated Assessment has not been completed for a number of the issues, for which the Licensee has agreed to provide the results of studies, analyses and evaluations needed by the NRC Staff for its assessments and decisions. All of these issues are of such a nature that hardware backfits may be required for their resolution. The resolution of these issues will be addressed by the NRC Staff in a supplemental report.

Many of the issues still being evaluated by the Licensee relate to the effects of extreme environmental phenomena such as earthquakes, floods, and tornadoes, since the La Crosse plant was not designed to resist these phenomena at the levels that would be required by current criteria.

Use was made of a limited Probabilistic Risk Assessment (PRA) in connection with the NRC Staff's evaluations. Since a plant-specific PRA was not available for the La Crosse plant, the techniques used were similar to those used in similar circumstances for other plants in the SEP. As in those other cases, we believe that the NRC Staff's use of PRA was appropriate and that suitable use was made of the results.

Our conclusions regarding the SEP review of the La Crosse plant are as follows:

1. The SEP has been conducted in such a manner that the stated objectives have been achieved for the most part for the La Crosse Plant.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

Rm 1152

May 18, 1983

Mr. William J. Dircks
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Dircks:

SUBJECT: ACRS REPORT ON THE ACCIDENT SEQUENCE PRECURSOR STUDY AND THE USE OF OPERATIONAL EXPERIENCE

During its 276th meeting, April 14-16 and its 277th meeting, May 12-14, 1983, the Advisory Committee on Reactor Safeguards reviewed some of the recent work and proposed programs related to the evaluation and use of operational experience, including the possible identification of accident sequences likely to lead to core damage. In addition to the report, NUREG/CR-2497, "Precursors to Potential Severe Core Damage Accidents: 1969-1979" (also known as the ASP Study), the Committee had the benefit of discussions with representatives of Oak Ridge National Laboratory (ORNL), Science Applications, Inc. (SAI), the Institute of Nuclear Power Operations (INPO) and the NRC Staff. Subcommittee meetings on the subject were held on February 9 and March 9, 1983. The latter meeting also included a summary report by a representative of the Electric Power Research Institute (EPRI) on an EPRI workshop held on the subject on February 28 - March 1, 1983. The Committee also had the benefit of the documents referenced. The Committee undertook this review at the request of the Office of Nuclear Regulatory Research.

The Accident Sequence Precursor Study

The ASP Study, which was performed by ORNL and SAI for the NRC, was initiated largely in response to a recommendation by the NRC's Risk Assessment Review Group to try to use operational experience to improve reactor safety. The ASP Study represents an interesting and useful first effort to categorize and numerically rank the significance of operating experience reported in Licensee Event Reports (LERs). It endeavors to apply the methodology of probabilistic risk assessment (PRA) to such reported experience in a pioneering attempt to quantify an area of investigation previously treated primarily by qualitative means. To this extent, it appears to be a worthwhile effort to reduce dependence on subjective evaluation, but it is not without shortcomings.

The original objectives were consciously vague. However, with the completion of the first phase of the work and the ensuing review and discussion, the purpose of the ASP program as now defined by the NRC Staff is to develop

and apply a formalized, systematic methodology for the evaluation of nuclear plant operational experience data. This methodology will be used to identify precursors to potentially serious accidents or incidents and to estimate their occurrence frequency. The specific objectives include the following:

- identification of strengths and weaknesses of existing PRA studies by the use of operational experience;
- interpretation of operational experience in terms of margins to core damage;
- evaluation of average, industry-wide risk as it emerges from operational experience.

Thus, the NRC Staff views the ASP program as complementary to the nuclear plant PRAs currently being performed by industry and by the NRC.

The contents of the ASP Study (NUREG/CR-2497) can be divided into three parts:

- definition and use of a screening process to select "significant" event sequences from the large mass of LERs available for the 1969-1979 decade;
- quantitative ranking, based on a definition of probabilistic margins to severe core damage, of those events judged significant for the above period;
- use of the probabilistic margin to core damage to formulate an experience-based, "industry-wide" estimation of severe core damage likelihood as it existed in the same 1969-1979 period.

The data base upon which this first phase of the ASP program was based was composed of approximately 19,400 computerized abstracts of LERs dated 1969-1979. A reading and selection process guided by written criteria and knowledgeable judgments was used to reduce this base of short abstracts to a group of 529 event reports before examining the complete documentation which composes each report. Given the superficial quality and scope of most LER abstracts, it is to be anticipated that a significant number of events were probably overlooked during the event selection process. The study estimated that at least 10% of the significant events were missed.

With regard to the screening process, the ASP Study concentrated on the identification of sequences containing multiple failures and resulting either in the complete loss of one function required to prevent core damage or in the degradation of more than one such function.

All available LER documentation was reviewed for the group of 529 events selected and a determination based on written criteria was made which led to the identification of 169 events as precursors to potential severe core damage. The events finally selected were categorized and mapped onto standardized (generic) event trees that described the sequence of possible mitigating actions or events following a given transient or accident (e.g., loss of offsite power, occurrence of a small LOCA, loss of feedwater, or steam line break). The event trees chosen were not plant-specific but did represent likely transient or accident situations which could have been affected by the identified precursors.

Initiating event frequencies, failure time intervals, and functional failure probabilities were developed where practical from information contained in the full LER documentation itself. Quantitative ranking of the postulated events was then performed by evaluating the conditional probability of severe core damage given the event considered. The parts of an event sequence that actually occurred were treated deterministically in this evaluation, whereas the parts that did not occur were treated probabilistically, but with an updating of the failure rate information available from prior PRA studies with the data contained in the selected event sequences. The top 52 events had conditional probabilities of 10^{-3} or greater and were selected as significant precursors for the purposes of the Study. Credit was not given in the standardized fault trees for plant-unique systems or differences, or for possible alternative pathways or processes that might have influenced the outcome. This is a recognized shortcoming.

An industry-wide, severe core damage (SCD) probability estimate was derived in the ASP Study by summing the conditional probabilities of SCD for the selected events and dividing the result by 432, the number of reactor-years of operation over the time period included in the Study.

A good deal of controversy has arisen concerning both the methodology and the numerical results obtained for the precursors quantified in NUREG/CR-2497. The authors of the report have recognized that their methodology, as employed, is subject to possible "overcounting" and have estimated that this might make their probabilistic results high by a factor of up to three. Other methods of analyzing the data have been suggested but none appears to be unequivocally "the right one" and the actual degree of "overcounting" remains difficult to quantify.

INPO applied the same methodology to the "significant" precursors identified by ORNL but made different interpretations of the data and employed detailed event sequences that frequently differed from the ASP Study with regard to available mitigative features. INPO obtained average numerical results which are substantially lower than those in the ASP Study, as well as a different ranking of the events in order of significance. Representatives of the NRC Staff reported a partial list of results that tended to support the ASP Study in some cases and the INPO Study in others.

Some of these differences will be reduced or will disappear as part of the continuing dialogue. However, it is clear that subjective opinion plays a considerable role in the ASP Study methodology, as it does in PRA in general, and large differences are likely to remain even if the same detailed event trees are employed by each group.

There exists a considerable school of thought in the industry that ASP Studies should be performed using plant-specific methods and data. This suggestion has its attractions. However, suitable plant-specific PRAs do not exist in sufficient number, and plant-specific data will be sparse. Thus, the resources required for event-significance quantification on a plant-specific basis would be far larger than those used in the ASP Study. Also, even plant-specific studies would be forced to rely on generic data in many instances, and there does not appear to be a universally accepted recipe for this procedure. Hence, there appears to be merit in both plant-specific and generic interpretation of operational experience, each properly executed.

It is noted that neither the ASP Study nor the INPO Study included an analysis of the uncertainty in the reported results or an assessment of their sensitivity to assumptions made in the analysis. This lack can be understood in a status report. However, we believe that future efforts along this line should include a careful evaluation of such uncertainties and sensitivities.

It should be noted that the authors of NUREG/CR-2497 were not trying to predict the future risk in making an estimate of the average likelihood of core damage; rather, they were trying to evaluate the existing risk during the years 1969-1979. Hence, improvements in safety made since 1979 are not reflected in the report. Because of differences in the methodology used and because each plant has its own safety characteristics (which may differ from the generic event trees used in the ASP Study), the results of the ASP Study should not be directly compared with those of the PRA for a specific plant.

The INPO SEE-IN Program and the Work of the NRC Office of Analysis and Evaluation of Operational Data (AEOD)

The ACRS reviewed briefly the INPO SEE-IN program and the work of AEOD in order to better understand their relationship to the ASP program. Both the SEE-IN program and the work of AEOD are largely qualitative and focus on an examination of specific operational events (or sets of similar events), screen these events for significance, and strive to extract lessons which can be used directly in improving safety. The efforts of both groups have been productive and both groups continue to improve their methodology.

Both efforts are needed, since they serve different users and provide somewhat different perspectives.

Some Concluding Comments and Recommendations

1. It was reasonable for the first phase of the ASP Study to develop somewhat specific objectives as the work progressed, since it was exploratory research. The future ASP program is expected to have better defined, albeit still flexible, objectives.

2. There is a class of information which the AEOD and SEE-IN programs may be treating only in part and which the ASP program largely has not considered. The ACRS suggests that further evaluation be made as to whether adequate attention is being given to operational experience in connection with matters such as the following:

   a. where improved maintenance practices are needed (e.g., the Salem circuit breakers),

   b. whether there are adequate diagnostic capabilities to indicate impending problems and how to control them,

   c. whether plant operating procedures are adequate and effective,

   d. deficiencies in engineering design, construction and application of plant systems, controls, and components,

   e. the stage at which accident consequences can be controlled most effectively,

   f. effects of plant aging on safety, and

   g. quality deficiencies that may have been overlooked.

3. The objectives of the AEOD work, the INPO SEE-IN effort, and the ASP program should be coordinated so that significant gaps do not exist when the combined efforts are considered.

4. The ASP program has highlighted deficiencies in most existing PRAs even though some of these weaknesses had been previously recognized. Examples include operator errors of commission and complex scenarios such as the Browns Ferry fire. Strong interaction in both directions between PRAs and the ASP program is needed in the future. Much more work is needed before quantitative results from the ASP program can be considered to be meaningful. However, there is merit in continuing to attempt to obtain average estimates of risk, as well as a quantitative ranking of event significance, by analyzing operational experience.

5. Some attention should be given to the following methodological issues:

- Single failures should not be discarded automatically, as single failures of high frequency might be symptomatic of bad maintenance practices, or plant vulnerability to "external events" and other common causes or "bypass mechanisms." In particular, the screening process should be altered so that the ASP program includes single failures of on-line systems of special importance to safety.

- The ASP Study considered only precursors which could lead to core damage, so that experience with containment was not a factor. Such experience would, of course, become relevant were one to attempt to evaluate public risk. The ACRS recommends that the scope of future studies be extended to cover mitigation systems such as the containment.

- Sensitivity and uncertainty evaluation should be included as an integral part of the ASP program itself. A special effort should be made to identify the principal causes of uncertainty.

- Since there appears to be no single, agreed-upon way to perform the quantitative evaluation of risk, either in relative or in absolute terms, the evaluation should be attempted in several alternative ways and studies made to explain the key reasons for differences which may materialize. The issue of "blending" plant-specific and generic data is one area in which one could gain beneficial insight by pursuing such a "multi-faceted" approach.

- An evaluation should be performed and published to make clear the reasons for the different results obtained for conditional severe core damage probability by the ASP Study and the INPO critique (INPO 82-025) for the 52 significant precursors.

- The handling of human error probability is highly subjective. It is potentially a large source of difference in the estimates developed. The matter should be specifically reviewed from several points of view, including: the usefulness of a common mode of treatment as one alternative in each such study to place similar studies on a comparable basis; the development of failure models more applicable to real occurrences; and the inclusion of errors of commission in the event trees.

6. The importance of the qualitative aspects of the evaluation of operational data and experience must continue to be emphasized. Study efforts should examine the chain of events in important incidents in terms of root cause.

7. The ACRS endorses continuation of studies of operational experience, both qualitative and quantitative.

Sincerely,

Jesse C. Ebersole
Acting Chairman

References:

1. Science Applications, Inc. Oak Ridge National Laboratory, "Precursors to Potential Severe Core Damage Accidents: 1969-1979, A Status Report," Prepared for USNRC, NUREG-CR-2497, Vols. 1-2, dated June 1982.

2. Institute of Nuclear Power Operations Confidential Report, "Review of NRC Report: 'Precursors to Potential Severe Core Damage Accidents: 1969-1979, A Status Report,' NUREG/CR-2497, dated September 1982

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

May 17, 1983

Mr. William J. Dircks
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Dircks:

SUBJECT: ACRS SUBCOMMITTEE REPORT ON THE USE OF POTASSIUM IODIDE (KI) AS A THYROID BLOCKING AGENT

On April 28, 1983 the ACRS Subcommittee on Reactor Radiological Effects met with the NRC Staff for discussions on the issue of stockpiling and predistribution of potassium iodide (KI) for potential nuclear power plant accidents. This issue had previously been discussed during the ACRS joint Subcommittee meeting on Class 9 Accidents and Reactor Radiological Effects, February 22, 1983. Representatives from the Food and Drug Administration (FDA) and the National Council on Radiation Protection and Measurements (NCRP) also participated in the Subcommittee meeting on April 28.

On the basis of these discussions, the Subcommittee has summarized its comments and a copy is enclosed for your information. Also appended for your information are copies of the written comments on this subject submitted to the Subcommittee by Dr. Eugene Saenger, representing the NCRP, and Dr. Bernard Shleien, representing the FDA. We trust these comments will be helpful to the NRC Staff.

Sincerely yours,

Jesse C. Ebersole

Jesse C. Ebersole
Acting Chairman

Enclosures:
1. "Comments on the Use of Potassium Iodide (KI) As a Thyroid Blocking Agent," by ACRS Subcommittee on Reactor Radiological Effects - 4/30/83
2. "Comments on the NRC Document: Radiation Protection - Thyroid Blocking - Draft" by Eugene L. Saenger, 4/28/83
3. "Recommendations on the Use of Potassium Iodide as a Thyroid-Blocking Agent in Radiation Accidents - An FDA Update," by Bernard Shleien

COMMENTS ON THE USE OF POTASSIUM IODIDE (KI)
AS A THYROID BLOCKING AGENT

Prepared by

Subcommittee on Reactor Radiological Effects
Advisory Committee on Reactor Safeguards
April 30, 1983

The ACRS Subcommittee on Reactor Radiological Effects met on April 28, 1983, with representatives of the NRC Staff, the Food and Drug Administration (FDA), and the National Council on Radiation Protection and Measurements (NCRP) to discuss the evaluation being conducted by the NRC Staff relative to the use of potassium iodide (KI) as a thyroid blocking agent during reactor accidents. On the basis of this meeting, the Subcommittee prepared the following comments:

1. Estimates presented to the Subcommittee by the NRC Staff indicate that, for accidents covering a wide range, the greatest projected health impact (cancer fatalities) on the population as a result of passage of the plume would be due to whole body exposures as contrasted to exposures to the thyroid. If this is true, it raises questions as to the basis for the use of thyroid blocking as a primary emergency protective action. This matter should be reevaluated before proceeding further with the development of an agency position on this issue. Of particular importance in this reevaluation is the consideration of the newer source term information which should result from current NRC research.

2. The risk/benefit analyses conducted by the NRC Staff on this subject do not appear to be compatible with (or comparable to) approaches used in evaluating other aspects of nuclear emergency planning. For example, if the same evaluations were made, would there be justification for the conduct of emergency drills or the installation of warning sirens? Similarly, the question could be raised as to whether there would be justification for population evacuations.

3. The NRC should also be encouraged to join with the Federal Emergency Management Agency (FEMA) in developing definitive guidance for state and local agencies on these matters. Provision of KI to onsite nuclear power plant workers and to potential emergency rescue teams appears to be justified. Mechanisms for the distribution and instructions on the use of KI by the general public, however, should be left to the judgment of state and local public health and/or emergency planning officials. Stockpiling or predistribution of KI to the public should not be made an NRC licensing requirement.

4. Review of this subject by the Subcommittee indicated that several additional technical questions remain to be answered. These include determinations relative to:

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a. The shelf life of KI and possible methods for extending it.

b. The question of the potentially greater carcinogenic effects of thyroid exposures from external sources as contrasted to those from internally deposited radioiodine.

c. The sensitivity of the cost/benefit calculations, assuming a uniform population density, versus more realistic population distributions.

Comments on the NRC Document:
RADIATION PROTECTION - THYROID BLOCKING - DRAFT
Eugene L. Saenger, M.D.
April 28, 1983

In 1972 the NCRP formed an ad hoc committee on Thyroid Blocking resulting in the issuance of NCRP Report 55. In addition to three thyroidologists, a nuclear engineer and a public health physician, aid was received from a number of staff members of NRC. The final report was reviewed by the NCRP membership numbering about 65 scientists and physicians. The report recommended a blocking dose of 130 mg of KI (100 mg of I) per day upon advice of public health authorities if the radiation dose to the thyroid approaches 10-30 rad. This daily dose is to be continued under guidance of public health authorities. Sheltering, evacuation and milk surveillance were also discussed as were possible complications of KI therapy. No specific recommendations for stockpiling and distribution were made.

The FDA reviewed, expanded and finalized these recommendations between 1977 and the present.

In March and April 1979 at Three Mile Island there was escape outside of the containment vessel of so small an amount of radioactive iodine that it did not constitute a threat to the population either within the plume or ingestion zones. Since then there has been speculation (at least from this physician's viewpoint) as the possible occurrence of a deficit in release of radioiodines.

Meanwhile the potential use of KI has been criticized in several ways. Aldrich and Blond of the NRC in several publications have indicated that KI is not cost effective in preventing either thyroid nodules or thyroid cancer. Yalow (Yalow RS. Potassium iodide: Effectiveness after nuclear accidents. Science 218: 742, 1982) regards the use of KI as dangerous pointing out that the number of serious iodine effects will exceed the number of thyroid tumors which may be prevented.

The American Thyroid Association although agreeing that chemical blocking of the thyroid gland is a reasonable protective measure if administered under appropriate circumstances recommends that the decision point should be a potential thyroid dose of 100 rad.

An opposite viewpoint has been expressed on a number of occasions by Von Hippel (Von Hippel F. Potassium iodide policy. Science 218: 6, 1982) who believes that KI should be distributed over a radius of 100-200 miles. His argument focuses on his interpretation of equal efficacy of ^{131}I as compared to external x-irradiation in the production of thyroid abnormalities and certain other calculations regarding the dissemination of radioiodines which differ from those of the Reactor Safety Study (RSS).

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The RSS has been critically reviewed on several occasions and was criticized in part as being not sufficiently conservative (NUREG/CR-0400 [see p. A-2 of NRC draft]). Rasmussen, however, pointed out that the RSS prediction was conservative in its preductions in comparison with the actual experience at TMI (Hubner K, Fry S: The Medical Basis for Radiation Accident Preparedness. Elsevier/North Holland, New York, 1980). More recently Lewis has indicated that the RSS is conservatively biased (Scientific American, March 1980). More recent studies (NUREG 2239) suggest that the major areas of contamination may well involve sectors within a 2-5 mile radius, i.e. that more planning and drills will be useful close to the fence line. A probability is assigned to the ingestion zone of about 1-2 orders of magnitude less than in the plume zone.

The current NRC draft is based on some assumptions that require further discussion and clarification. It is quite unclear why the entire U.S. population needs to be supplied with KI. In addition to the lowered probability of release of radioiodines from the containment vessel (NUREG 2239) it seems likely from the extensive meteorological studies that only a few sectors downwind would be involved. Also it does not seem reasonable that Governmental agencies, either local or Federal, should be required to stockpile and distribute a blocking agent. The governmental agencies do not necessarily plan to furnish transportation for evacuation although they have certainly cooperated well with the private sector and service agencies such as the Red Cross in many crises in the recent and distant past. These points will be analyzed further below but the present draft seems unrealistic in these two important parameters based on relatively recent NRC documents.

Currently we are attempting to purchase the 130 mg KI tablets as OTC preparations in the Cincinnati area. This effort has been unsuccessful. Certainly there are many reasons for this difficulty. At the very low cost and presumably low price, it will be necessary to generate a large volume of sales in order to provide the participating drug companies with a cost effective product. These concerns should not be penalized for their apparent lack of willingness to participate in this effort. It is important to provide some marketing opportunities. For example over the past decade it became necessary for DOE to subsidize the production of pharmaceutical grade DTPA compounds in amounts suitable for therapy of transuranic element contamination because the FDA would not accept the manufacturer's claim of efficacy for other purposes. A similar role for KI hardly seems justifiable although this possibility may require consideration.

In order to make some further estimates of the need for KI based on a given dose, say 20-100 rem to the thyroid, the total population in the vicinity of 36 power reactors was summed from NUREG 1856 as shown in Table 1. Using many of the assumptions in the NRC draft document except for the need to supply the total

U.S. population each with one tablet some further calculations follow.

POPULATIONS AROUND POWER REACTORS
From NUREG 1856* July 1981

Radius	Permanent	Transient	Row Totals
2 mile	99523	18313	117836
5 mile	490601	88479	579080
10 mile	2136016	301854	2437870
Column Totals	2726140	408646	3134786

*Fifty two reactor sites are listed but only 36 supplied population data

As an example derived from the NRC draft document, with a U.S. population of about 200 x 10^6 persons, the number within a 10 mile radius of 36 reactor sites is 3/200 = 1.5% of U.S. population. It would seem within reason to estimate that no more than this fraction would require KI protection based on the low probability of a release of ^{131}I. To carry these projections further with a probability of a reactor accident of 10^{-5}/yr for 36 reactors listed in the above report, one can calculate the cost as 36 x 10^{-5} x 0.015 x \$200 x 10^6 = 1080/yr = \$1080.00 at 10¢ per tablet for a 10 day supply.

It is true that ^{131}I can possibly involve a portion of the ingestion zone but probably not within a period of 24-48 hours which would give sufficient time for sheltering, evacuation, distribution of KI and redistribution of existing milksheds.

Estimate of thyroid nodules: BEIR III (p.301) estimates 12 cases per 10^6 PY per rad. Using the above population within the 10 mile zone, about 3 x 10^6, and without correction for age, race, sex or latency, an estimate would be 3 x 10^6 x 12 x 10^{-6} per rad per year or 36 cases/rad in a given year. Again without corrections about 12 cases/rad/yr might be malignant, about 1-2 cases/rad/year would be fatal.

At a cost of \$1080 the cost benefit ratio would be 1080/36 = \$30.00 per nodule per rad per year. If one were to multiply these values by an average lifetime of 50 years after exposure, the excess cases prevented would be 36 x 50 years or 1800 and the cost benefit ratio would become 1080/1800 = 60¢/case assuming 100% effectiveness of KI and blocking at 1 rad or less. If 30 rad is used as a threshold cost becomes 2¢/case.

If one were to include the ingestion zone based on Tables 1 and 2 there is a change in the above calculation of a factor of

10-100 that would increase the cost benefit ratio to $6.00-$60.00.

In a period when there are enormous investments in nuclear power plants many of which are not completed for various reasons and great concern by citizens concerning safety, it does not seem useful to engage in debates concerning the protection of the thyroid gland between agencies of the Government. Several steps are recommended to aid in the resolution of this problem:

1. A more thorough study of the effects of policies of other governments, principally those in Europe, should be made preferably by an international conference held here or by individual visits.

2. There should be further studies on stability under different conditions of packaging, climate, storage and other factors of various iodine preparations.

3. In the drills as required in NUREG 0654 study of methods of distribution of iodine compounds as compared to sheltering and evacuation should be carried out.

   Particular attention should be paid to the recommendations of masks, filters, wet towels and other home remedies to filter out airborne iodine compounds in whatever physico-chemical states they exist. These casual proposals, however simple and inexpensive they may seen, offer serious threats to large classes of persons including infants and young children, patients with chronic cardiac and pulmonary diseases, the elderly and persons who are or may easily become emotionally disturbed.

4. A trial of distribution by local authorities as compared with over the counter sales should be carried out in two comparable areas to determine the efficiency and costs to the public of these two different methods.

5. It is essential to define far more precisely than has been done before the population which may be at risk for thyroid exposures above 25 rad at each reactor site.

E.L. Saenger, M.D.
April 28, 1983

Recommendations on the use of Potassium Iodide as a Thyroid-Blocking Agent in Radiation Accidents An FDA Update

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The Food and Drug Administration (FDA) published a notice in the Federal Register on December 15, 1978 entitled "Potassium Iodide as a Thyroid Blocking Agent in a Radiation Emergency." In this notice FDA invited manufacturers to submit New Drug Applications (NDA) for potassium iodide products and announced the availability of labeling guidelines. The notice had no immediate effect, however, on public discourse (1). It was only after the accident at Three Mile Island that FDA received any NDAs. Approval of NDAs opened further debate about the use of potassium iodide. The past 3 years have produced vigorous, often heated discussion about the role of the drug as a thyroid-blocking agent, with many opinions expressed about the population in whom the drug should be used, the thyroid dose at which it should be used, and the methods for making it available. The controversy did not reach its heights until FDA issued its final recommendations on the use of potassium iodide as a thyroid-blocking agent in a radiation emergency (2). This is not surprising because the agency had to make some decisions with which there was no unanimity. These decisions involved the weighing the benefits of using potassium iodide with the radiation risk to the thyroid gland from iodine-131. There are, in addition, other controversial matters concerning the stockpiling and distribution of

ATTACHMENT 3

potassium iodide on which the FDA properly did not take a position. This is because these matters do not fall within the jurisdiction of the FDA. At this juncture it is appropriate to review FDA's recommendations to understand the agency's positions and the likely implications for the use of potassium iodide. At the same time, it is also appropriate to review the related issues upon which FDA did not take a position.

Safety and Effectiveness

In its initial notice on potassium iodide the FDA stated that potassium iodide is safe and effective for use as a thyroid-blocking agent in a radiation emergency in which radioiodines are accidently released into the environment (1). This finding is based on FDA's review of the information on the ability of stable iodine to saturate the thyroid gland and on possible side effects of the drug in the published literature dating back to the 1800's, including reports in the FDA's Voluntary Reporting System on adverse drug reactions.

There is general agreement that the drug can achieve almost complete (greater than 90 percent) blocking of radioactive iodine uptake by the thyroid gland. This effect can be obtained by the oral administration of 130 milligrams (mg) of potassium iodide (65 mg for infants under one year of age) just before or at the time of exposure to iodine-131. A substantial benefit (i.e., a block of 50 percent) is attainable if administered up to three to four hours after acute exposure.

On the issue of potassium iodide's safety, however, there is less agreement. For example, Dr. Yalow raised significant questions concerning the risk of

potassium iodide in her comments on a draft of FDA's recommendations (3) and more recently in a summary of testimony at a Congressional hearing chaired by Mr. Markey of Massachusetts held on March 5, 1982 (4). Dr. Yalow suggested that based on experience by Curd and the incidence of hypocomplementemic vasculitis in rheumatoid arthritis that there might be 6 in 10,000 acute, severe reactions from the medically unsurpervised administration of potassium iodide. Dr. Yalow's reference to Curd was to a report in the Annals of Internal Medicine of December 1979, by John G. Curd, M.D., et al. titled, "Potassium Iodide Sensitivity in Four Patients with Hypocomplementemic Vasculitis"(5). Metabolic studies of radio-labeled proteins were conducted in 126 patients of which four (3 percent of the patients in the study group) were suspected of being sensitive to potassium iodide because they had repeatedly developed urticaria and other allergic symptoms after multiple administrations. The potassium iodide was administered in 0.5 gram doses on multiple occasions in serial fashion to block thyroid uptake of iodine for purposes of the study. Two of the four patients were selected to evaluate the possible association of potassium iodide sensitivity with urticaria, hypocomplementemia and vasculitis. The patients were given 1 gram of potassium iodide initially and then potassium iodide was administered twice a day until sensitivity reactions occurred or for 2 days. Challenge with 1.0 gm of potassium iodide in the two sensitive patients precipitated an allergic type reaction of moderate severity in one patient, and a prolonged severe systemic illness in the other. The authors believed both reactions were caused by the potassium iodide. Ten control patients did not present the same reaction, tending to confirm the impression of potassium iodide sensitivity in the two patients.

Thus, Curd's study confirmed potassium iodide sensitivity in two patients who had had repeated, multiple, large (0.5 gram) administrations of the drug.

The incidence of hypocomplementemic vasculitis is a rare condition. At the University of Cincinnati Medical Center, a referral institution, with over 2,000 patient beds and hundreds of thousands of outpatient visits per year, only 12 individuals are seen per year with this condition (6). Based on Curd's study (in which 3 percent of the patients had a severe reaction) and the incidence cited above, the figure of 6 per 10,000 appears to be greatly over estimated.

Potassium iodide in large doses (300-1200 mg daily for adults and 100 mg or more for children) has been widely used for years in the long-term management of bronchial asthma and other pulmonary disorders. Individual reports of complications from iodide administration in the medical literature for the most part do not identify the size of the patient population taking iodides from which the cases have been drawn. While cases are undoubtedly under-reported, the number of reports of adverse reactions from potassium iodide received by the FDA has been low. The incidence of significant adverse reactions from short-term administration of potassium iodide to humans in daily doses of 65 or 130 mg is unknown but is expected to be low (2). (It is important to distinguish the much more common reports of reactions to organic bound iodine compounds).

The known potential for potassium iodide to cause serious side effects in a small sensitive population is not sufficient grounds from which to conclude,

or even postulate, a significant and quantifiable proportion of serious reactions (or deaths) in patient populations which would be exposed to much smaller doses of the drug over a limited time and which would not be expected to include patients of this category. (Most are under a physician's care).

The adverse reactions to potassium iodide can be grouped into thyroid and non-thyroid effects. For example, the thyroid reactions include: (1) Iodide goiter with or without hopothyroidism (especially neonatal goiter); (2) Hyperthyroidism (Jodbasedow syndrome); and (3) Hypothyroidism. The nonthyroid reactions include: (1) Dermatologic and mucous membrane reactions; (2) "Iodide Mumps" and miscellaneous reactions; and (3) Serum sickness type hypersensitivity and vascular reactions. The occurrence of most side effects and toxicities appears to be proportional to dose and duration of treatment, and except for anaphylaxsis most are not expected under the pharmaceutical dose regimen recommended for thyroid-blocking.

In view of the benefit to be derived from the use of the drug to block the thyroid in a radiation accident, the FDA concluded that the benefit/risk ratio favors the use of the drug for that purpose when the projected radiation dose to the thyroid gland from radioiodines released into the environment is equal or greater than 25 rem. This conclusion is discussed further under Thyroid Radiation Risks.

Thyroid Radiation Risks

There is a paucity of human data relevant to the induction of radiation effects from iodine-131, particularly in children. Two epidemiological studies are available which attempt to quantify the risk of thyroid cancer

from iodine-131 irradiation. Data from Rallison et al. (7) and Holm (8) did not show any increase of thyroid cancer in their irradiated populations with estimated mean thyroid doses of 18 to 160 rem, respectively, from nuclear weapon fallout or iodine-131 diagnostic procedures when compared to the spontaneous thyroid cancer incidence. Holm's study population was mostly adult at the time of irradiation (8). As adult thyroid cells do not normally undergo cell division, their radiogenic thyroid cancer risk would not be expected to be the same as those in infants and children. Furthermore, about a third of the Holm's irradiated population received thyroid hormone therapy, surgery, or both following irradiation, which may also have contributed to the low observed thyroid cancer incidence.

In the Rallison et al. study, an estimated average thyroid dose of 18 rem from fallout from atmospheric nuclear weapons tests was believed to have been received by his study population (7). The actual thyroid doses have not been adequately determined in this population. This is evidenced by the continuing controversy surrounding radiation effects around the Nevada test site from weapon testing in the 1950's and 60's. Moreover, the follow-up period of 14 years in his irradiated population may not be adequate for full radiogenic thyroid cancer expression.

In an earlier case study of Marshall Islanders exposed to nuclear weapon fallout, Conard et al. found that within 22 years after exposure 24 of 68 persons exposed on Rongelap had developed thyroid nodules and four of these were thyroid cancer (9). Thyroid doses for the Rongelap people were estimated to be from 220 to 450 rads for an adult and 700 to 1400 rads for a child (9). These doses include those from radioiodines (including short-lived radioiodine isotopes) and an estimated external gamma dose of 175 rad.

The risk of thyroid cancer in man from external x-ray has been demonstrated in numerous epidemiologic studies (10,11,12). For young adults treated with x-rays, the risk of thyroid cancer is estimated at 1.6 to 9.3 excess cases of thyroid cancer per 10^6 PY-rem (13). (PY is a person-year of follow-up). Ron and Modan reported an increased incidence of thyroid cancer at a mean thyroid dose of about 9 rads in about 11,000 children irradiated for tinea capitis and followed up for 12 to 23 years (10).

The impression that iodine-131 is not as effective as x-rays in thyroid cancer induction was based mainly on the observations of Doniach in rats and Maxon et al. in man (14,15). Doniach's conclusion that x-ray was 10 times more effective than iodine-131 in thyroid cancer induction was based on the results of three rat studies in which an estimated thyroid dose of approximately 10,000 rem from iodine-131 was thought to be equivalent to that of 1000 rem from external x-rays. In these studies, a surviving proportion of less that 28 percent of the animals was left after a 15 month or a 2 year study. Such low survival and small number of animals per dose group can lead to serious biases in the estimation of cancer incidence. The effect of cell killing at the high radiation doses due to the iodine-131 versus the lower dose used for external x-rays was not accounted for by the Doniach study (14). Similarily, the relative thyroid cancer susceptibility of 70:1 between x-ray and iodine-131 as reported by Maxon et al. in children could also be due to difference in cell killing at the higher iodine-131 doses used in the comparison. (The x-ray dose ranged from 0-1500 rem, whereas the iodine-131 doses were approximately 9000 rem).

Thus the risk of thyroid cancer following external x irradiation of the thyroid has been well established, but the risks from internal exposure to

iodine-131 are not. Until now the impression was that iodine-131 was much less effective than external x-rays in thyroid cancer induction. The rationale usually given for this difference is a low dose rate and an uneven dose distribution in the thyroid gland from internal exposure to iodine-131. However, data from a recent animal study by Lee et al. (16) demonstrated that the dose-response functions in thyroid cancer induction in rats from both iodine-131 and external x-rays are similar within the dose range of 0-1000 rem.

The paucity of human data relevant to the induction of radiation effects from iodine-131, particularly in children, has convinced the FDA that it is prudent to employ risk estimates from external irradiation studies in reaching the conclusions upon which its recommendations are based.

From this evidence, the FDA concluded that the risks of radioiodine-induced thyroid nodules or cancer at a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment outweigh the risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency. The FDA recommends that potassium iodide in doses of 130 mg per day for adults and children 1 year and above, and 65 mg per day for children below 1 year of age, be considered in those persons likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released to the environment (2). A projected dose of this magnitude is equal numerically to the Environmental Protection Agency's upper Protective Action Guidance[1]

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[1] EPA Protective Action Guides call for sheltering, evacuation and controlled access as protective actions when the total accumulated thyroid doses are projected at 5 to 25 rem for the general population (17). The lower level is used if there are no major constraints. If local constraints exist, the higher value is employed. However, the EPA guides do not specifically note the use of potassium iodide as an appropriate protective action for the general population.

level for the general public (17) and the United Kingdom's National Radiation Protection Board's upper level proposed for potassium iodide use (18). These Agencies expect some protective action to be taken at a projected radiation dose of 25 rem or greater to the thyroid from radioiodines released into the environment.

In its comments on a draft of FDA's final recommendations, the American Thyroid Association wrote, "Based upon available data, it would seem unlikely that clinically significant thyroid disease would result from individual thryoid exposure of less than 100 rads. To provide an added measure of protection for children and pregnant women, a radiation dose of 50 rads to the thyroid is suggested as a theshold for iodine blockade for this group (19)." This comment made before the publication of the results of the animal studies of Lee et al., and is thus based on the earlier studies of comparative iodine-131 and external x-ray thyroid risks already mentioned. In any case, given that the most sensitive segments of the population should be protected the opinion of the American Thyroid Association and the conclusions of the FDA are not very far apart.

Over-the-Counter Status

FDA approved potassium iodide for use in radiation emergencies as a non-prescription drug because the agency was able to conclude that adequate directions for its use by the public could be written.(1) A second reason for the decision was to provide the necessary flexibility to state and local officials considering distribution of potassium iodide as part of their emergency response planning.

Even so, potassium iodide for thyroid blocking is unlike other non-prescription drugs: Its safe and effective use depends on a determination by local public health authorities that a radiation emergency has occurred or is likely and that projected release levels of radioiodines would be such as to make the benefits of using of the drug outweigh its risks. For that reason, special labeling for the consumer must accompany the drug. This labeling states, among other things, that it should be taken only when public health authorities so direct.

To date there are three manufacturers holding approved new drug applications for this product. The three are Carter-Wallace, Roxane Laboratories, and Anbex, Inc. of New York City. In November 1982, Anbex Inc. began running newspaper advertisements in the Harrisburg, Pa., area, the site of the Three Mile Island plant, offering to sell potassium iodide tablets for radiation protection directly to the public. In press reports by the Associated Press and Harrisburg area newspapers, Anbex said it also planned to promote the tablets soon in Peoria, Ill.--a city not near a nuclear power plant--to compare public response with that of the Harrisburg area. If interest was strong, a nationwide marketing campaign by Anbex was planned.

While the other FDA-approved manufacturers of potassium iodide for thyroid blocking (Carter-Wallace and Roxane Laboratories) voluntarily agreed at the time of approval to limit distribution to state and local officials and nuclear power plant operators, Anbex did not agree to follow such restrictions. Because of Anbex's campaign, FDA notified these other manufacturers that it no longer expects them to abide by their voluntary agreements.

Although potassium iodide is also available as an ingredient in prescription drugs for treating asthma and other lung disorders, these prescription products provide much higher doses than are necessary for thyroid blocking in a radiation emergency. Also, the enteric coated form of many of these delays absorption through the digestive tract, possibly impeding the drug's effectiveness in a radiation emergency. Furthermore, prescription products are not labeled properly for this specific use.

Distribution, Stockpiling, and Cost Effectiveness

Perhaps the most heated aspects of the controversy surrounding the use of potassium iodide are stockpiling and distribution, and cost effectiveness. The Department of Health and Human Services (and hence the FDA) is charged with providing guidance to State and local governments on the use of potassium iodide, including the radiation dose at which its use should be considered, but the Department's role is not to define whether or not potassium iodide should be, stockpiled or distributed. These responsibilities properly reside with the States. Federal guidance in these matters however, is to be provided by the Federal Emergency Management Agency and the Nuclear Regulatory Commission; not the FDA (20).

On these matters FDA's final recommendations state: "Each State has the responsibility for formulating guidance to define if and when the public should be given potassium iodide and instructed to use it. In preparing guidance and making rules, State or local officials should inform citizens of the nature of the radiation hazard and of the potential benefits and adverse effects of potassium iodide. In those instances where State or local officials administer or direct the administration of the drug to

citizens the same kinds of issues as to liability may arise as have arisen in public immunization programs (21, 22). Citizens should be provided with, and encouraged to read, the information leaflet, which accompanies the drug. Notice of the availability of guidelines on the information leaflet has been published in the Federal Register (1,23)." Also, the Department and the FDA recently approved a draft of the Federal Radiological Preparedness Coordinating Committee's (chaired by FEMA) national policy statement that reiterated this stand (24).

Once it is determined to include potassium iodide in emergency plans, the two issues regarding supply are: 1) stockpile or don't stockpile and if the decission is made to stockpile, then: 2) predistribute or don't pre-distribute. The advocates of stockpiling say that proper preparedness planning requires that an adequate amount of potassium iodide tablets or solution be available within the State or, where there is more than one nuclear power plant, at several sites within the State. From these sites, in the event of an emergency, it can be rapidly distributed to persons who are living in areas where they may be a risk of receiving doses to the thyroid of 25 rem or greater. The non-stockpile advocates point out that stockpiling is expensive. It requires the initial purchase of the drug plus warehouse expenses. Since drug products have finite lifetimes, replacement of stockpile stocks when the drug product reaches its expiration date, requiring additional investment is also needed. Non-stockpile advocates argue that in the event of an emergency, the drug can be procured quickly from the manufacturer or, conversely, the drug should be stockpiled, but by the Federal government or the utility, and not by the State.

The case for pre-distribution is based upon the premise that if and when the drug is needed, it would take too long for it to reach the affected population from large stockpile locations and, to be sure that people will have it when they need it, each person, family, or household should have its own supply readily available. Such pre-distribution to the household level would solve one logistics problem, but as those who oppose pre-distribution argue, it would just substitute a different set of problems. They point out that if the drug was pre-distributed to households it would likely get lost or be forgotten when the emergency was at hand or it could be out of date.

According to information from the Conference of Radiation Control Program Directors, State emergency plans have addressed these supply issues in the following manner (25):

Stockpile for use by emergency workers: 31 States

Stockpile for public use, but do not pre-distribute: 6 States

Pre-distribute to public immediately residing around a nuclear power plant: 1 State

Adopted a position not to use for anyone: 4 States

Adopted a position not to use for the general public only: 5 States

The survey covers 37 States which have an Emergency Planning Zone within their jurisdiction.

Overseas, the United Kingdom has stockpiled but not pre-distributed the drug for public use. Sweden has made the drug available and pre-distributed it to populations around reactor sites.

Another argument made against the pre-distribution of the drug is that the probability for a reactor accident which would release radioiodine to the environment is very low and that, in any case, previous estimates of the amount of radioiodine released in an accident are too high. The probability issue is beyond the context of this discussion. Concerning the source term (amount of radioiodine released), it is reasonable to conclude that if less radioiodine than previously estimated is released in a reactor accident, that the zone in which potassium iodide would be useful would be greatly reduced, but it would not disappear altogether.

The cost effectiveness of stockpiling potassium iodide has also been raised as a significant issue for concern. An NRC study indicates that the use of potassium iodide as a thyroid-blocking agent on a large scale may not be cost-effective (26). This study determined cost-effectiveness from the cost of the drug, the number of thyroid nodules that could be avoided by its use, and the probability of occurrence of a catastrophic nuclear power plant accident. The conclusion of the study is that if the probability of a nuclear power plant accident of the type that releases consequential quantitites of radioiodine is one in about 1,400 years with the present number of operating nuclear power reactors, the large scale stockpiling and distribution of potassium iodide would not be cost-effective. Of course, the cost-effectiveness of other emergency measures (for example, alerting and warning systems) should also be considered for a fair comparison. The probability of occurrence of an accident influences the cost-effectiveness of all emergency planning measures including the use of potassium iodide. If the probability of a serious reactor accident were greater, then the

cost-effectiveness of stockpiling potassium iodide would be more favorable. Although production, distribution, and stockpiling costs on a national basis may be significant, the procurement of potassium iodide tablets has been estimated to cost about 40 to 75 cents per person dose package. Potassium iodide solution in 1 ounce bottles, containing enough drug for an entire family may cost less on a per person basis.

Conclusion

In view of the current state of knowledge on radiation risks to the thyroid and the benefits and risks of potassium iodide as a thyroid-blocking agent, there is no new compelling evidence that suggests a need to modify the current FDA recommendations on the use of potassium iodide as a thyroid-blocking agent. The Department of Health and Human Services and the FDA concur with a draft statement of Federal policy that incorporates the principle that individual States are responsible for formulating policies concerning the stockpiling and distribution, as well as if and when to use this drug in radiation accidents that release radioiodines to the environment.

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