

ALASKA LEGISLATIVE COUNCIL FILED 1962

1662 SJ SB 29. - SB 41

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NOTICE OF PROPOSED CHANGES IN THE REGULATIONS OF  
THE DEPARTMENTS OF NATURAL RESOURCES,  
ENVIRONMENTAL CONSERVATION AND FISH AND GAME;  
THE BOARDS OF FISHERIES AND GAME AND THE  
ALASKA COASTAL POLICY COUNCIL

Notice is hereby given that the Departments of Natural Resources, Environmental Conservation and Fish and Game; the Alaska Coastal Policy Council, and Boards of Fisheries and Game, under the authority vested by AS 16.05.-020(1) and (3); AS 16.05.050; AS 16.05.251; AS 16.05.255; AS 16.05.270; AS 16.05.050-060; AS 16.20.120; AS 16.20.240; AS 38.05.020(b)(1); AS 44.19.893; AS 44.19.894; AS 46.03.-020(10); AS 46.40.040 and AS 46.40.200, propose to jointly adopt regulations in a new Title 22 of the Alaska Administrative Code ("Interagency Regulations"), and to amend 6 AAC 80, to implement and make specific the above-cited statutes as follows:

(1) Adoption of 22 AAC 10, which would designate most permits issued by the above entities for construction or operation of a facility as either "Class I" or "Class II" permits, and would require that Class I permits be issued in 30 days and Class II permits be issued in 65 days. These deadlines may be extended if:

(a) a project involves complex issues requiring additional time for review;

(b) a public hearing is held;

(c) the agency and the applicant mutually agree in writing to a more lengthy review period;

(d) the deciding agency processes the application jointly with a federal agency.

The regulations of each agency and board will specify whether each particular permit will be a Class I or Class II permit, and the applicable regulations in 22 AAC 10 will then apply.

The following list sets forth the proposed classification of permits for each agency:

CLASS I

CLASS II

Department of Natural Resources

1. General Land Use Permit  
(AS 38.05.330)

Formerly:

Div. of Parks:

- Assembly Permit
- Disturbance of Natural Materials
- Field Archaeology Permit
- State Park Use Permit
- Access Route Permit
- Special Events Permit
- Special Land Use Permit
- Non-compatible Use Permit

Div. of Forest, Land & Water Management

- Right of Way Permit
- Special Land Use Permit
- Tideland Permit
- Personal Use Permit
- Trapping Cabin Permit
- Miscellaneous Land Use Permit
- Stock Driveways Permit
- Grazing Permit

2. Burning Permit
3. Temporary Water Use Permit
4. Plan of Operations Review Outside Coastal Area of the State.

1. Plan of Operations Review Within Coastal Area of the State. \*/

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\*/ However, public notice will not be provided unless required by federal law in order to obtain a binding coastal management consistency determination.

CLASS I

CLASS II

Department of Fish and Game, and Boards of Fisheries and Game

1. Habitat Protection Permit

None

Formerly:

- Anadromous Stream Permit
- Fish Passage Permit
- Critical Habitat Permit
- Refuge Permit
- Sanctuary Permit

Alaska Coastal Policy Council (as administered by the Division of Policy Development and Planning)

1. When made by the division, coastal management consistency determinations on direct state and federal activities involving less complex matters

1. When made by the division, coastal management consistency determinations involving  
A. private applicants; and  
B. direct state and federal activities involving more complex matters.

Department of Environmental Conservation

1. Air Quality Control Permit to Operate AS 46.03.020

1. Variance to Air Quality Standards AS 46.03.170

2. Air Quality Control Permit to Open Burn AS 46.03.020

2. Solid Waste Management Permit AS 46.03 100

3. Permit to Interfere with Salmon Spawning Streams and Waters AS 16.10.010

3. Short Term Variance (Water Quality Standards) AS 46.03.020

4. Plan Review of Sewage Treatment Works AS 46.03.020

4. Waste Disposal Permit AS 46.03.020

5. Subdivision Plan Review 18 AAC 72.065

5. 401 Certification Certification of Reasonable Assurance AS 46.03.020

6. Surface Oiling Permit AS 46 03.020

6. Oil Discharge Permit for Scientific Purposes AS 46.03.020

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|---|---|
| 7. Plan Review of Public Water Systems AS 46.03.020 | **7. Oil Discharge Contingency Plans AS 46.04.030   |
| 8. Seafood Processing Plant                         | **8. Proof of Financial Responsibility AS 46.04.040 |
| 9. Milk, Milk Products, Process                     | 9. Permit to Apply Pesticides AS 46.03.020          |
| 10. Slaughterhouse Operation                        |   |
| 11. Food Service                                    |   |
| 12. Swimming Pool Plan Approval                     |   |

The procedures governing issuance of Class I permits do not require public notice, and require interagency review only on an informal basis and only when coastal management issues are involved; Class II permits, however, do require public notice and interagency review. Public hearings may be held on either class of permits if required by law or if the agency determines that good cause exists. Articulation of the basis of the decision must be provided at the time of issuance for Class II permits, and in the event of appeal for Class I permits.

In addition, the proposed uniform procedures define the rights of the applicant and the public, and the procedural protections available. These include: (1) deadlines for request of additional information from the applicant, for receipt of comments by agencies and the public, and for appeal of permit decisions; (2) maintenance of a record file for each permit application which for Class II permits will include a record of all communications between the state and persons not employed by the state; the contents of the record file shall be public information unless required by law to be confidential; (3) provision for interested parties to keep informed and remain actively involved throughout the permit review and appeal processes; (4) assignment of "great weight" to comments from state agencies in their primary areas of expertise. In addition, applicants and persons directly and adversely affected by a permit decision have the right to appeal. However, this appeal right is conditioned upon raising a material issue, and the appellant must have raised his issues on appeal at available stages in the decision-making process. The proposed regulations establish two types of appeal: a "Class A" informal appeal, and a

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\*\* Public notice will not be provided.

"Class B" appeal involving more formal adjudicatory procedures. The regulations of each agency will specify which class of appeal applies to a particular permit decision, and a Class A appeal may be taken even if a Class B appeal is available.

Finally, the proposed regulations substantially change the coastal management decision making process of the state. Under existing regulations, the state is required to ensure that state actions, including permit and license decisions, are consistent with the state's coastal management program. The proposed regulations establish a process for arriving at a single, conclusive consistency determination for most activities by dividing responsibility for coastal management decisions among the agencies on the following basis:

(a) Division of Policy Development and Planning

When an activity requires preparation of an environmental impact statement by the federal government, or when it occurs on the OCS, the consistency determination will be made by the Division of Policy Development and Planning.

(b) Department of Natural Resources

Except when (a) applies, when an activity requires the disposal of state land or an interest in state land, consistency determinations will be made by the Department of Natural Resources as part of its existing responsibility to determine that the disposal is in the "best interests" of the state. Consistency determinations relating to "plans of operation" will also be made by DNR.

(c) Department of Environmental Conservation

For activities occurring in the coastal area which require neither an EIS, a land disposal, nor a plan of operations, the consistency determination will be made by the Department of Environmental Conservation as part of any necessary "Section 401" determination under the federal Clean Water Act.

(2) 6 AAC 80.900(20) is proposed to be amended to change the definition of "feasible and prudent" to conform to that phrase's meaning in sec. 4(f) of the Department of Transportation Act of 1966 (49 U.S.C. § 1653(f)).

These regulations are comprehensive and complex, and this summary attempts to highlight only their major points. A longer executive summary has been prepared. Persons interested in natural resource permit reform are strongly encouraged to obtain a copy of the longer summary and the regulations from:

Alaska Department of Law  
Attn: Special Assistant Attorney  
General Jon K. Tillinghast  
Pouch K, State Capitol  
Juneau, Alaska 99811

These regulations are a major component of Governor Hammond's permit reform project, the goals of which are to unify, simplify, expedite and make fairer state natural resource decision-making. Suggestions other than those proposed in the regulations are encouraged. Specifically, interested persons are urged to comment upon the question of whether state agency comments on pending federal permits should be made solely by the same agency delegated coastal management responsibilities in the regulations. This is an issue which may be resolved in the final regulations.

Written comments on the regulations may be submitted to the Alaska Department of Law at the above address at any time prior to February 27, 1981. Notice is also given that any person interested may present oral or written statements or arguments relevant to the action proposed at hearings to be held at the following times and places:

FAIRBANKS - time: 7:00 P.M. to 10:00 P.M.

place: Chamber of Commerce Log Cabin  
Basement meeting room  
555 1st Avenue

date: February 4, 1981

ANCHORAGE - time: 7:00 P.M. to 10:00 P.M.

place: Municipal Offices - Assembly Hall  
3500 East Tudor Road

date: February 6, 1981

JUNEAU -

time: 7:00 P.M. to 10:00 P.M.

place: City Borough Council Chambers

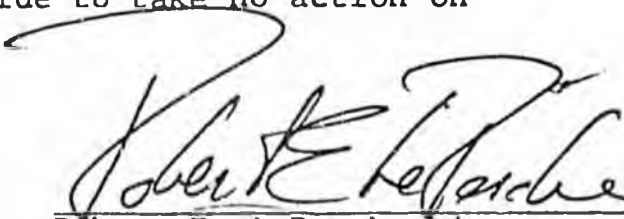
date: February 9, 1981

It is estimated that this action will require increased appropriations as follows: FY 1980-81 \$79,000.00; FY 1981-82 \$302,000.00

The above agencies, boards and council, upon their own motion or at the instance of any interested persons, may at any time after February 27, 1981 and without further notice adopt the proposals in a manner consistent with the scope of this notice, or may decide to take no action on them.


DATE:

8 January 1981

  
Robert E. LeResche  
Commissioner  
Department of Natural Resources

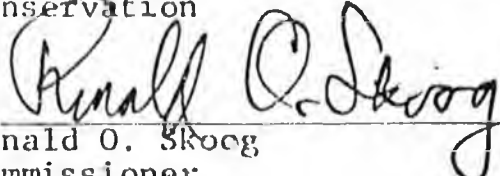
DATE:

8 January 1981

  
Ernst W. Mueller  
Commissioner  
Department of Environmental  
Conservation

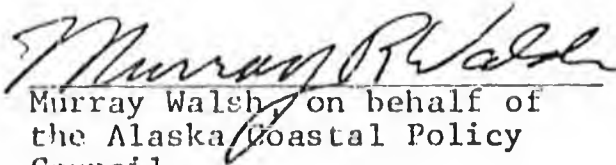
DATE:

9 Jan 81

  
Ronald O. Skoog  
Commissioner  
Department of Fish and Game,  
and on behalf of the Boards  
of Fisheries and Game

DATE:

8 January 1981

  
Murray Walsh on behalf of  
the Alaska Coastal Policy  
Council

UNIFORM PROCEDURAL REGULATIONS  
EXECUTIVE SUMMARY

A. Intent and Background of Regulations

The purpose of this executive summary is to describe the background and intent of the uniform procedural regulations (22 AAC 10) for which public notice of proposed adoption was jointly issued by four state agencies on January 9, 1980. This summary will also briefly discuss major areas of concern which have emerged with respect to the regulations.

These regulations are the product of a permit reform project established by Governor Hammond on June 17, 1980, and are intended to achieve these primary goals:

1. Establishment of the shortest feasible deadline for the issuance of state permits for natural resource development.

The regulations provide that the departments of Natural Resources, Fish and Game and Environmental Conservation, and the Division of Policy Development and Planning within the Office of the Governor, referred to in the regulations as "resource agencies," must classify their permits as either a "Class I" or "Class II" permit. The regulations provide that Class I permits must be issued within thirty days of receipt of a completed application. Class II permits must be issued within sixty-five days. The published informative summary of the regulations contains the agencies' proposed classifications. The regulations provide for extensions of these deadlines in certain limited cases. As part B of this summary discusses, the regulations attempt to provide sufficient safeguards to insure that an extension will only be given when it is absolutely necessary.

2. Establish uniform permit procedures.

Currently, permit and appeal procedures vary dramatically not only between, but within state agencies. Uniform permit procedures make it far easier for applicants, and the public in general, to do business with state government. If adopted, these regulations would supplant all procedural material contained in the regulations of the particular agencies involved, and a host of administrative orders, interagency agreements, and informal and written understandings. The Class II procedures, the most complex

in the regulations, replace this voluminous mish-mash with a scant 1 1/2 pages of uniform regulations. The regulations of each agency will state the permit requirement; describe the substantive criteria under which that permit will be granted, and will classify the permit. The regulations in proposed 22 AAC 10 will govern administrative proceedings for that permit.

3. Explicitly define the rights of the applicant, and other persons in the permitting process.

Currently, some state agencies have no procedural regulations governing the issuance of their various permits. Other requirements which may significantly affect the outcome of the permit application are found in administrative orders, interagency agreements and other documents and understandings not contained in the administrative code. Sometimes, procedural protections are left to agency "discretion". This approach causes two problems. First, it arguably contravenes the Alaska Administrative Procedure Act which provides, in AS 44.-62.640(2), that all rules of general applicability should be contained in regulations. Second, it promotes misunderstanding between the agency and the public, and in the long run, threatens unnecessary litigation. The proposed regulations attempt to explicitly define the rights of all the parties while avoiding unnecessary procedural burdens.

4. Streamlining the states coastal management decision making process.

Under existing regulations (6 AAC 80.010(b)) implementing the state's Coastal Management Act (AS 46.40), before a state agency may issue a permit for an activity in the coastal area, it must determine that the activity is "consistent" with the state coastal management standards found in 6 AAC 80. Additionally, under sec. 307(c) of the federal Coastal Zone Management Act (16 U.S.C. § 1456), federal agencies must obtain a "consistency determination" from the state before federal permits or licenses in the coastal area may be issued. The state's requirement (6 AAC 80.010(b)) is intended to implement AS 46.40.200, which seeks to insure that state actions, including permit and license decisions, will be consistent with the state's coastal management program. The approach taken in 6 AAC 80.010(b), however, has created both unnecessary duplication and the potential for inconsistent state positions on a project. If an activity needs four state permits, for example, 6 AAC 80.010(b) requires each of the four state agencies to make "consistency determinations" in the course of its

permit proceeding. There is little reason for one finding to be made four times. Moreover, under current procedures, the state will make a fifth consistency determination when a federal agency issuing a permit seeks state certification under sec. 307(c) of the federal act. Compounding this unwarranted duplication is the fact that these multiple consistency determinations need not agree. In October, 1980, the Alaska Coastal Policy Council, by resolution, requested the administration to devise an approach whereby one determination, for both state and federal law purposes, would be made on a project, with that determination being made, to the extent feasible, within existing permitting processes. Article 5 of the proposed regulations contains the administration's proposal. That proposal allocates responsibility for making "one time" consistency determinations in the following manner:

a. When an activity is of such significance as to require the preparation of an environmental impact statement by the federal government, a consistency determination should be made by the governor's office. Accordingly, responsibility in these cases would be vested with the Division of Policy Development and Planning. This is a narrow sphere of responsibility.

b. Under existing law, the Department of Natural Resources cannot dispose of an interest in state land until it finds that the disposal would be in the "best interests" of the state. AS 38.05.035(a)(14). The coastal management standards are essentially a subset of the many factors which as a whole constitute the "public interest". Thus, as a matter of law and practicality, it seems most logical, except in cases involving EIS preparation, to vest "consistency determination" responsibility for state land decisions exclusively in the Department of Natural Resources. Moreover, after many disposals, particularly for oil and gas leases, the Department of Natural Resources will require a "plan of operations" to be approved by the department. To provide continuity in this regard, the regulations provide that the consistency determination on activities authorized in that plan will also be done by DNR.

c. There are a wide range of activities occurring in the coastal area which neither require the preparation of an environmental impact statement, nor are authorized by a state land disposal or plan of operations. The primary impact which these activities will have on the

coastal area is often related to water quality, and those water quality impacts must normally be permitted by either the Environmental Protection Agency or the Army Corps of Engineers under the federal Clean Water Act. Section 401 of that act requires that the Department of Environmental Conservation "certify" that the issuance of that federal license or permit will not violate state water quality standards. By vesting coastal management consistency determination authority for this large residual of activities in the Department of Environmental Conservation, the regulations will allow that determination to be made within the already necessary "sec. 401" process, and by the agency with the primary expertise over the probable primary impact of that activity.

An example of the functioning of the administration's proposal might be helpful. When the Department of Natural Resources considers holding an offshore oil and gas lease sale, that agency will make the only determination as to whether the sale is consistent with the state standards. When a successful lessee seeks to construct an offshore exploratory well, it will apply to the Department of Natural Resources for approval of the plan of operations with respect to that well and related facilities. DNR will then make a conclusive consistency determination on the placement of that well and related facilities. Some of these facilities obviously will need other permits from other agencies. At a minimum, placement of the well offshore will need a permit from the Corps of Engineers. When a consistency determination is requested of the state by the Corps of Engineers under sec. 307(c) of the federal Coastal Zone Management Act, the Division of Policy Development and Planning will utilize the determination already made by the Department of Natural Resources. Moreover, if any other state permits are necessary for an activity approved in the plan, the state permitting agency will not conduct a consistency determination, since the question of whether that activity is consistent with the standards has already been determined by the Department of Natural Resources.

It is the hope of the administration that these regulations will result in major progress in making state permitting procedures more efficient, explicit and fair. Working sessions on these regulations have already been held with industry, environmental and public interest groups. All of these groups endorse the four goals of the regulations. A December 3, 1980, working draft of the regulations has been substantially revised to accommodate many of these groups' recommendations. Inevitably, however, none of the

groups are totally satisfied with the product. Several serious issues regarding the regulations remain. Generally, certain oil industry commentators are unsatisfied with the regulations because they are perceived to (1) give unwarranted recognition to the rights of the public and local governments in the permitting process, and (2) allow state renewable resource agencies to comment on federal permit applications and to have excessive input on state natural resource decisions. Conversely, the federal Office of Coastal Zone Management, and certain environmental commentators, believe that the regulations give inadequate protection to all of the above interests.

The second part of this summary discusses several of the major areas of concern regarding the regulations, and the rationale for the treatment of those concerns given in the current proposal. These rationales, of course, should not be taken as inflexible "positions". The whole purpose of the public notice process is to generate debate on these issues.

## B. Major Issues Raised by the Regulations

### 1. Division of Policy Development and Planning responsibilities.

As the previous section of this summary suggests, the assignment of authority to make "conclusive" coastal management consistency determinations will result in particular state agencies taking a role of primary authority on coastal management issues. Interest groups, depending upon their orientation and past experience, have come to view particular state agencies as more sympathetic to their interests than others. As a result, commentators to date have offered quite variant positions on where that "ultimate authority" should lie.

At the outset, the administration has attempted to develop a "consistency determination" procedure which ensures true interagency consultation. This process was developed to ensure uniformity in the interpretations of the state coastal management standards, and to lessen the practical effect of the choice of actual decision-makers. This effort, described in subsec. (2) of this section, has been alternatively perceived by some industry groups as excessive, and by the federal Office of Coastal Zone Management as insufficient.

Regardless of the safeguards taken in the regulations, the question of the choice of decision-makers has remained prominent. Certain oil industry commentators have recommended that the Governor's Office should have no responsibility for making consistency determinations where a private applicant is involved. The rationale for the administration's proposal has been previously stated.

Because of the narrowness of the DPDP sphere of responsibility (see section (A)(4)(a) above), it will remain almost universally true that the Department of Natural Resources will have exclusive coastal management authority over its own land disposal actions. This aspect of the draft regulations originated as the primary industry proposal on coastal management and was endorsed by the administration primarily because of the legal and logical relationship between the consistency determination and the "best interest finding" under AS 38.05.035(a)(14) (see above). This alternative has been criticized by environmental groups, and by the federal Office of Coastal Zone Management, which believe that the Department of Natural Resources will face a conflict of interest in making a consistency determination on its own proposals. Because in this instance an agency will be reviewing the consistency of its own activities, it is particularly vital that procedural safeguards be placed in the decision making process.

Little criticism has been offered to date of the placement of authority with DEC over the large "residual" category of activities needing sec. 401 certification under the Clean Water Act.

## 2. The coastal management procedural protections.

There is a danger in "dividing" coastal management responsibilities. The standards themselves (6 AAC 80) are capable of diverse interpretation, although the proposed regulations attempt to tighten these standards by giving a meaning to the phrase "feasible and prudent" which has judicial interpretation. Nonetheless, there will remain a possibility that diverse bodies of administrative precedent might develop as to the meaning of the standards. Second, if the coastal management decision-making process is not sufficiently disciplined, the statutory mission of the particular agency having jurisdiction becomes substantially more important, which makes, in turn, the possibility of a realistic solution to the "duplication" problem all but impossible to achieve.

Several protections have been proposed in response to these problems. First, a disciplined interagency review process had been provided for Class II permits, where most consistency determinations will be made. Section 130. The regulations provide that if the deciding agency (for example, DNR on state land matters) rejects a recommended course of action by a sister agency, the reasons for that rejection must be clearly articulated. See sec. 160(3). Additionally, the deciding agency must accord "great weight" to the comments of its sister agencies, but only if those comments are within the primary area of expertise" of that agency. Section 130(c). This provision has generated both criticism and misunderstanding. The definitions section of the regulations (900) makes it clear that this provision is not intended to give any other agency actual or practical decision-making authority. This is because no commenting agency is deemed to have "primary area of expertise" on the decision itself. The most often used example of the operation of this requirement is with respect to plan of operations approval by the Department of Natural Resources for an oil and gas lease. Let us suppose that the Department of Fish and Game comments that a particular drilling activity will have adverse wildlife impacts, and that to mitigate those impacts a seasonal drilling restriction should be imposed. The deciding agency will normally be required to defer to Fish and Game comments concerning actual or likely adverse impacts, since that is clearly within that department's "primary expertise". However, deciding upon a seasonal drilling restriction depends upon a balance of the magnitude and likelihood of the impact occurring, economic, engineering and other factors. The balancing is solely the province of the deciding agency -- in this case DNR -- and, as a result, the Department of Fish and Game will not be entitled to "great weight" on its recommended seasonal drilling restriction.

Oil industry commentators are unhappy with this safeguard -- even given the narrow definition of "primary area of expertise", which was provided by the Division of Minerals and Energy Management. They see the protection as giving the Department of Fish and Game, if not a "veto", at least unwarranted new authority. Certainly, it gives no commenting agency a "veto" (see above). Moreover, the comments fail to recognize that both sound administrative practice, and federal law, require meaningful coordination of all state agency interests in making coastal management decisions. Presently, that "coordination" occurs by virtue of the ability of other agencies to make their own "consistency determinations" on the same project reviewed by DNR.

They won't be able to do that anymore, and a more substantive role must be provided other agencies in the forum for making the one determination which will bind the entire state.

Conspicuously, the federal Office of Coastal Zone Management has forcefully urged that the state should, and perhaps must go substantially further in ensuring adequate consideration of the views of other agencies. Their primary recommendation has been to require that, for example, DNR plan of operations decisions be appealable to a multi-agency board, on which Fish and Game would presumably sit, and through which they would have a functional veto authority.

To ensure uniformity of interpretation of the guidelines, the regulations provide (sec. 920(9)) that interpretations of the meaning of the guidelines offered by the Office of Coastal Management will be entitled to great weight. This provision has caused little criticism. What has been severely criticized, however, is sec. 570(b), which provides that local governments with an approved coastal management programs will be entitled to great weight on questions of whether a particular activity is consistent with that program. Certain oil industry representatives have insisted that even when a local government has an approved program under AS 46.40, state agencies should not defer to that local government on questions of consistency within its municipal boundaries. The Office of Coastal Management strongly believes that this view is inconsistent with the intent of the act, which is to increase the voice of local government in state decision-making once a program has been approved. The disagreement over sec. 570(b), then, is as much one of law as policy, and the Department of Law is researching the issue.

Finally, until recently, the oil industry has been very critical of the fact that review of plans of operations will be classified as a "Class II" permit, since public notice (sec. 120) is provided for Class II permits. Currently, public notice of proposed plans of operations is not provided by the Department of Natural Resources, and they have seen sec. 120 as imposing a new and unwarranted procedural requirement. Public notice is being provided in certain cases for plans of operations solely because it is required by federal law. As noted previously, in the course of its plan of operations review, the Department of Natural Resources will be performing a consistency determination which will serve as the state's "determination" for federal permit purposes as well. 15 CFR § 930.61 requires that a state

consistency determination on a proposed federal permit or license must be predicated on public notice. Under the proposal, however, public notice will not be provided even when the activity is in the coastal area, if no related federal permit is necessary. For these plans, then, a decision could be made immediately after expiration of the twenty-one day agency review period in sec. 130. Once aware of this federal requirement, criticism of this aspect of the regulations has diminished.

Any significant dilution of these protections may raise serious questions as to the continued legality of the state's program under federal law. The interests of the public, and of local governments in particular, would be severely injured if this were the case.

### 3. Extensions of permit deadlines.

As noted previously, the regulations provide that the Class I and II permit deadlines may be extended under certain circumstances. These circumstances are:

a. Complex projects. Section 020(a)(1) and 020(b) of the regulations provide that the permit deadlines may be extended if the commissioner of the agency certifies that the project is too "complex" to be adequately reviewed within the timeframe otherwise allowed. There is little disagreement that a sixty-five day review of, for example, the TransAlaska Pipeline, is less than adequate to protect the public interest. This exception was recognized and jointly endorsed by industry and the administration in House Committee substitute for SB 548, a permit reform bill considered in the last legislature. As a safeguard, sec. 020(b) requires that the commissioner's office itself make the certification, and also requires the commissioner to establish the "shortest feasible time" in which review can be completed. Subsequent extensions are not permissible.

b. A maximum twenty day extension is possible if a public hearing is held on the project. Section 020(a)(2), sec. 050(f). There are two reasons for this provision. First, the agency will often not know whether a public hearing is warranted until late in the decision-making process. For example, with Class II permits, the agency will often not know the intensity of public concern until the close of its public notice process, which will often be thirty-five to forty days after the

application has been received. See sec. 120(b)(3). That would leave, at most, twenty-five days to decide upon a hearing, provide adequate advance notice of the hearing, hold the hearing and thoughtfully consider the comments received. That is simply impossible to do. By allowing the additional twenty days at most, the agency can realistically hold a meaningful public hearing. Additionally, as noted in subsec. (4), criteria have been developed to limit the circumstances under which a hearing will be held.

Another reason for the twenty day public hearing "override" relates to the classification of permits themselves. Under SB 548, a third category of permits would be authorized -- Class III permits, which could be issued in ninety days. The primary value of the Class III permit category was to accommodate those permits (for the reasons stated above) for which a public hearing was periodically appropriate. The regulations abandon the Class III option. The administration feels that it is preferable to applicants to provide for an eighty-five day review period only in those cases where a public hearing is actually held, rather than lumping a whole class of permits into a ninety day category, even though in individual cases a public hearing would not be provided. Oil industry commentators nonetheless want this provision deleted, arguing that any public hearing should be held within the sixty-five day Class II period. That is not possible, if anything approaching adequate notice of the hearing is to be provided (see above). Indeed, environmental groups are deeply concerned that a twenty day extension is itself insufficient. If this extension were to be removed, Class III procedures would have to be written, and those permits now normally classified as Class II would be reclassified as Class III if there was any reasonable likelihood of a public hearing ever being warranted on a particular application.

c. Section 020(a)(3) provides that the deadlines can be extended by mutual agreement of the applicant and the department. This provision was originally inserted in SB 548 at the request of industry representatives, who envisioned certain circumstances where the administrative record might not be sufficient by the applicable deadline to sustain a granting of the permit.

d. Section 020(a)(4) authorizes agencies to enter into memoranda of understanding with federal agencies for the joint processing of applications even though the joint processing may result in differing deadlines from those imposed in regulations. However, under sec. 085, these memoranda are authorized only after the agency has weighed the impact of the differing procedures on the applicant. It would be counter-productive if these regulations precluded an agency from entering into a joint permit processing scheme with federal agencies simply because the existing regulations of the state and federal agencies were not compatible. This "exception" has generally been supported to date.

e. The deadline for issuing a permit may be "tolled" -- or suspended -- if the agency finds that, because of the unique nature of the project, additional information beyond that required in the application form is necessary. Section 030. Again, this exception was recognized in SB 548. Agency application forms and generally required attachments will provide, in almost all cases, enough information to reach a meaningful decision. Occasionally, an activity will raise unique issues which an agency must explore further if the permit is to be lawfully granted. It is not the intent of this section to allow or encourage fishing expeditions, or to demand veritable impact statements from the applicant. Any request for additional information must be linked to some information gap which prevents a sufficient assessment of the application under the decision-making criteria of the agency as contained in its statutes and regulations. Environmental groups have criticized sec. 030 because it, one, affords only one opportunity to request additional information and, two, requires that the information be sought early in the decision-making process. Oil industry spokesmen oppose this provision as providing "another loophole" for extending the deadlines.

#### 4. Public hearings and Appeal.

Section 050 of the bill establishes the criteria for holding a public hearing. Oil industry commentators have expressed concern that this provision requires that a public hearing be held in cases where hearings were not authorized in the past. To the contrary, this section is intended to constrain those situations in which permit proceedings will be extended through the holding of a

hearing. Currently, of course, any agency can hold a public hearing on any permit application, even if one is not required by law. The administration did not feel it sound to allow for a twenty day extension of the permit deadline for the holding of a hearing, without also limiting the situations in which a hearing would be appropriate. First, sec. 050(c) explicitly prohibits the holding of duplicative public hearings. Second, in determining whether to hold a hearing, the commissioner is explicitly required to consider the effect of a twenty day delay on the probable starting date of project construction (050(b)(4)) and whether the public concern for the project really has anything to do with the jurisdiction of the agency. Section 050(b)(2). From the applicant's point of view, these are beneficial new provisions.

Similarly, one oil industry spokesman has criticized the appeals sections of Articles 6 and 7 as expressly "legitimizing" the ability of a person other than the applicant to appeal a permit decision if he is directly and adversely affected. That criticism assumes that a member of the public has no such existing right, which could not be more wrong. A careful reading of secs. 610 - 620 in particular will disclose that the regulations in fact impose new, significant obligations on a potential public interest appellant. These requirements -- particularly the requirement of sec. 620 as to active participation throughout the decision-making process -- have been supported by industry. Thus, the criticism appears to be that the regulations should address limitations on the public's existing right to appeal, but should not "legitimize" the right itself.

#### 5. Permit amendments.

The regulations (sec. 080(c)-(d)) provide that changes to a permitted operation which involve significant new impacts require a new permit, while changes which do not involve significant impacts are treated as amendments which do not need public notice. Oil industry commentators have suggested that where the impacts are "insignificant", no communication with the agency should be necessary at all, and the activity should be allowed to proceed. That proposal would create a significant risk of misunderstanding, and perhaps litigation. Initially, the permittee would decide whether he felt this change was "significant". If he felt that it wasn't, he would proceed without notifying the agency. The obvious question is this: What if the agency detects the change, and disagrees as to its significance? The agency would then be free to take enforcement action for violation of its regulations.

6. "Automatic approval".

The regulations do not provide that if a permit deadline is missed, the permit is deemed "automatically issued". No issue surrounding these regulations has caused the administration more difficulty than this one. The administration supports effective enforcement of the deadlines imposed in these regulations. This is particularly so because the deadlines imposed are achievable, and those circumstances in which extensions are absolutely necessary have been clearly delineated.

To provide that permits are deemed automatically "issued", an approach endorsed by certain oil industry representatives and contained in SB 548, carries with it a great deal of disturbing baggage. First, such a provision would require a statutory change. It is not, at this time, a statutorily sufficient grounds for permit issuance that a deadline has been missed. Thus, absent a change in the law, a decision to issue a permit simply because a certain date has been missed would be arbitrary and capricious. Even if a statutory provision was provided, problems would remain. It could be argued that such a statute would be unconstitutional because it would deny a person seriously affected by the decision any real means -- administrative or judicial -- to influence the permit decision. Moreover, an agency with serious concerns over a permit near the close of the decision-making process might have no alternative but to deny the permit rather than to allow the thirtieth or sixty-fifth day to be reached. Third, if an agency should ever desire to issue a permit, but could not justify its decision based on the record, it might simply let the time run intentionally. Since the permit would be "automatically issued" by operation of the calendar, there would be no meaningful judicial review.

A suggestion has been made to alleviate this third problem by providing that judicial review under applicable criteria would still be permissible after the deadline had run, but that the court would review any conflicting evidence or opinion in a light "most favorable to the applicant." This suggestion has merit, but raises additional concerns as to whether the court would feel compelled to conduct a "de novo" review of the project, with resultant substantial delays in project approval.

Most fundamentally, the argument for "automatic approval" assumes that state employees will not use their utmost efforts to comply with their employers' rules and

regulations. Given adequate staffing levels, we believe that there will be little difficulty in meeting the requirements of these regulations. Before anything as difficult and uncertain as "automatic approval" is attempted, we believe that a year's trial period with adequate staff levels should be provided before more severe alternatives are attempted.

#### 7. State Comments on Federal Permit Applications.

A serious issue not addressed in the proposed regulations is the question of the degree to which state agency comments on federal permit applications should be constrained. Basically, the issue, as posed by the oil industry, is this: The regulations do provide that the state will speak with one voice on coastal management matters. However, an agency disenchanted with the results of that decision may still recommend its own terms and conditions -- or permit denial -- through comments on a federal permit application necessary for the facility. For legal or policy reasons, the federal permitting agency may feel compelled to accept that recommendation. As a result, an admitted possibility for "inconsistent" state positions remains.

It has been suggested that the agency with decisional authority on coastal management issues (*i.e.* DNR on state land matters) also have decisional authority on the text of state comments on federal permit applications (other than sec. 401 certifications by DEC) -- and that those comments be compiled at the time the consistency determination is made, so that the applicant will receive a single, inclusive and final "state position" on his project at that time.

The proposal would bring unquestioned benefits. It also has problems. The departments of Fish and Game (AS 16.05.020(2)-(3); AS 16.05.050(1)) and Environmental Conservation (AS 46.03.020(9)) arguably have direct statutory duties which this proposal could unlawfully impair. Second, since the Department of Fish and Game is never given the role of decision-maker on conclusive coastal management matters under the proposed regulations, denying that department its remaining avenue of direct influence would be seen by some as relegating that agency to a "second-class" status among its sister agencies. To the extent this perception is justifiable, demoting advocacy of wildlife concerns in Alaska to a subsidiary level is a policy decision of the most profound proportions.

It is anticipated that the final regulations will resolve this issue. Thus, public comment on this issue is strongly encouraged.

UNIFORM PROCEDURES FOR PERMITS,  
CONSISTENCY DETERMINATIONS AND APPEALS

ARTICLE 1. GENERAL PROVISIONS

22 AAC 10.010. SCOPE OF CHAPTER. This chapter establishes uniform permit and appeal procedures for permits issued by the departments of Natural Resources, Environmental Conservation, and the Office of the Governor, Division of Policy Development and Planning, and for habitat protection permits issued by the Department of Fish and Game. Substantive material pertinent to each permit requirement is contained in the regulations of each resource agency. Applicable permits will be identified in each resource agency's regulations as either a Class I or II permit. Those regulations will also contain additional procedural material germane only to a particular permit, and indicate whether a Class A or Class B appeal may be taken from an adverse permit decision.

22 AAC 10.020. DEADLINES ON PERMIT ISSUANCE. (a) This chapter establishes deadlines of 30 and 65 days respectively for an agency decision on each completed Class I and II permit application. These deadlines may be extended by the commissioner of the deciding resource agency if:

(1) the commissioner certifies, under (b) of this section, that the project for which the permit is sought involves substantial complex issues requiring additional time for review;

(2) a public hearing is held under sec. 50 of this chapter. However, extensions under (1) and (2) of this subsection may not be cumulated;

(3) the agency and the applicant mutually agree in writing to a more lengthy review period; or

(4) necessary steps in the decision-making process require more time than that specified in this chapter because the deciding agency is processing the application jointly with a federal agency pursuant to a memorandum of understanding entered into under sec. 085 of this chapter.

(b) A certification under (a)(1) of this section will specify the precise issues or conditions requiring prolonged review, and will establish the shortest feasible time in which that review can be completed. The deadline for reaching an agency decision will not be further extended.

22 AAC 10.030. ADDITIONAL INFORMATION. (a) If a deciding agency receives a completed permit application form which does not contain sufficient information concerning the project to allow the agency to determine compliance of the project with the agency's statutes and regulations, the agency will notify the applicant within 15 days of receipt of a completed application for a Class I permit, and within 30 days of receipt for a Class II permit. The notification will specify all information which the agency requires to determine compliance of the project with the agency's statutes and regulations.

(b) The notification will specify those peculiar facts or issues concerning the proposal which require more information than is provided on a completed application form.

(c) If a timely request under (a) of this section is made, the deadline for reaching an agency decision established in this chapter is tolled from the date of request to the date of full compliance with the request. Subsequent requests for additional information do not toll or extend the applicable deadline.

22 AAC 10.040. SIGNING OF APPLICATIONS. Unless otherwise specifically provided by statute, all permit applications must be signed as follows:

- (1) in the case of corporations, by a duly authorized representative responsible for the overall management of the project or operation;
- (2) in the case of a partnership, by a general partner;
- (3) in the case of a sole proprietorship, by the proprietor; and
- (4) in the case of a municipal, state, federal or other public facility, by either a principal executive officer, ranking elected official, or other duly authorized employee.

22 AAC 10.050. ORAL PUBLIC HEARINGS. (a) An oral public hearing on a permit application will be held if:

- (1) required by statute; or
- (2) subject to (c) of this section, good cause exists for holding a hearing.

(b) In determining whether good cause exists for the holding of a public hearing, the deciding officer will balance at least the following factors:

- (1) the substantiality of actual or, for Class I permits, likely public concern for the activity;
- (2) the degree to which those public concerns are relevant to the criteria for the agency's decision;
- (3) the scope and sufficiency of any pre-application consultation or hearing;
- (4) consideration of public concerns given at previous decision-making stages; and
- (5) the likely effect of delaying an agency decision in order to hold a hearing on the probable starting date of the activity.

(c) A public hearing will not be held under (a)(2) of this section if the deciding officer determines that:

- (1) a public hearing has been held on the project, or will be held in time for the results of that hearing to be considered by the deciding agency; and
- (2) a hearing held by the other agency has provided or will provide a sufficient forum for existing or likely public concern.

(d) The deciding officer or his designee will preside at the hearing. Order of testimony and time limitations will be established by the presiding officer. The deciding officer will consider only that testimony material to the permit decision being made.

(e) At the close of each witness' testimony, the witness may be questioned by the presiding officer and the department staff.

(f) The deadline for reaching an agency decision under this chapter will be extended by a maximum of 20 days if a hearing is held under this section.

22 AAC 10.060. DECISION OF APPLICATIONS. (a) Within the applicable time period provided in this chapter, the deciding officer will serve his decision on the applicant. The decision will include:

- (1) the permit, if it is the deciding officer's determination that a permit should be issued, including all conditions which the agency will impose on the permit; and
- (2) a statement that a person aggrieved by the officer's decision may take a timely Class A or Class B appeal, as applicable.

(b) A copy of the decision will also be served on any person who has timely commented upon the application or has served a written request on the agency for a copy of the decision.

22 AAC 10.070. PERMIT CONDITIONS. The deciding officer will, as authorized by statute or regulation, attach conditions to a permit, including design, operating, monitoring, inspection, sampling, access to records and reporting requirements, and, where authorized by statute, the posting of a performance bond or other surety, that he considers necessary to insure that all statutory and regulatory criteria will be met.

22 AAC 10.080. PERMIT LIMITATIONS. (a) The permit may state that it may not be assigned without prior written approval of the deciding officer. The deciding officer will grant approval under this subsection if he finds that the assignee has assumed the obligations of the permittee; the assignment will not result in an appreciable change in the operation; and the assignee is capable of meeting the permit conditions.

(b) A permit authorizes only that activity specified in the permit. Any change in the permitted activity which the permitting agency determines may result in significant adverse impacts from the permitted activity requires a new permit. Any other change in the permitted activity requires an amendment to the permit.

(c) Unless otherwise required by federal law, applications for a renewal or reissuance of or amendment to a permit will be treated as a Class I permit, except for extensions of a variance under AS 46.03.170. The deciding agency will, however, approve amendments to a permit on an emergency basis when necessary to protect public health, life, or property.

22 AAC 10.085. MEMORANDA OF UNDERSTANDING. A resource agency will, in its discretion, enter into memoranda of understanding with federal agencies for the full or partial joint processing of permit applications. A memorandum of understanding which would extend any deadline established in this chapter will not be entered into unless the commissioner finds that the costs of extension are outweighed by the reduction in procedural burdens on the applicant. A summary of the terms of any memorandum of understanding entered into under this section which extends any deadline established in this chapter will be included in the pertinent resource agency's regulations, and the memorandum will not be effective until the resource agency adopts the summary as provided in this section.

## ARTICLE 2. CLASS I PERMITS

22 AAC 10.090. DEADLINE FOR DECISION. An agency decision on a Class I permit application will be served under sec. 60 of this chapter within 30 days of service of a completed application on an individual or office specified in the deciding agency's regulations.

22 AAC 10.100. PROCEDURE. (a) Subject to sec. 570(e) of this chapter, inter-agency review and public notice are not required for Class I permits.

(b) All material prepared by or submitted to the agency with respect to the application will be placed in a record file, which will constitute the administrative record for the agency decision.

(c) Articulation of the basis for the decision is not necessary at the decision stage unless a public hearing has been held on the application under sec. 50 of this chapter,

in which case the basis for the decision will be briefly stated if the hearing produced material testimony adverse to the application.

(d) If a timely Class A or Class B appeal of the agency's decision is taken, the deciding officer, within 10 days of service of the notice of appeal, will serve on all parties an articulation of the basis of his decision, including terms and conditions, based upon the administrative record as it existed at the time of his decision.

(e) Each resource agency will maintain, and will update at least every two weeks, a file or files containing each still-valid Class I permit issued by the agency.

### ARTICLE 3. CLASS II PERMITS

22 AAC 10.110. DEADLINE FOR DECISION. An agency decision on a Class II permit application will be served under sec. 60 of this chapter within 65 days of service of a completed application on an individual or office specified in the deciding agency's regulations.

22 AAC 10.120. PUBLIC NOTICE. (a) After the service of a Class II permit application, the deciding agency will cause to be published at least one notice of the application in a newspaper of general circulation for the area which would be affected by the operation, and in other media the agency considers appropriate.

(b) Public notice under this section will include

(1) the name and address of the applicant, and the location of the proposed activity;

(2) a summary description of the proposed activity, including its type, size, and manner of operation;

(3) a statement that a person who wants to present his views to the deciding agency in regard to the application may do so by filing written comments with the agency within 30 days after the final publication of notice; and

(4) a statement that the non-confidential portion of the application is available for inspection and copying at cost.

(c) A copy of the notice will be sent to any unit of local government having jurisdiction over the proposed activity.

22 AAC 10.130. INTER-AGENCY REVIEW. (a) At the time of publication under sec. 120 of this chapter, the deciding agency will serve a copy of the application, or a summary of the application, on other interested resource agencies, and as required by law on other agencies.

(b) An agency served under (a) of this section may serve comments on the deciding agency, with a copy clearly identified as advisory comments to the applicant, within 21 days of receipt of the application. If the commenting agency recommends denial of the permit, or the inclusion of any term or condition, the factual or judgmental basis for that recommendation must be articulated.

(c) The deciding agency will accord great weight to comments of other resource agencies which meet the requirements of (b) of this section; are within the commenting agency's primary area of expertise; and were submitted by the commissioner's office of the commenting agency.

(d) The applicant may serve on the deciding agency a response to agency comments served under (b) of this section within 10 days of receipt of the comments. A longer response time will be allowed at the applicant's request; however, the granting of an extension correspondingly extends the deadline established in sec. 110 of this chapter.

22 AAC 10.140. RECORD FILE; UNTIMELY COMMENTS. (a) All material prepared by or submitted to the agency with respect to the application will be placed in a record file, which will, subject to (d) of this section, constitute the administrative record for the agency decision. Material required by statute or regulation to be kept confidential will be segregated from the publicly available portion of the file.

(b) Comments not received within the time periods specified in secs. 120(b)(3) and 130(b) of this chapter need not be considered by the staff or deciding officer.

(c) Nothing in this chapter may be construed as limiting an agency's authority to utilize its judgment or expertise in reaching permit decisions.

22 AAC 10.150. EX PARTE COMMUNICATIONS. Whenever practicable, communications between the applicant or other persons not employed by the state and an employee of the deciding agency regarding the application should be in writing. When any oral communication on any matter of substance is made, the agency employee will prepare a memorandum for the record file specifying the person with whom he communicated and the date and time of the communication, and a brief summary of the substance of the communication.

22 AAC 10.160. AGENCY DECISION. The agency decision will meet the requirements of sec. 60 of this chapter, and will contain:

(1) findings made by the state agency concerning the activity's compliance with applicable standards of the deciding agency;

(2) conclusions of the state agency which support its final decision concerning the permit application, including justification of any conditions to which the permit is subject; and

(3) a statement of the factual or judgmental basis for the rejection of any resource agency recommendation under sec. 130(b) of this chapter, or any significant and material recommendation made at a public hearing held under sec. 50 of this chapter.

#### ARTICLE 4. ENVIRONMENTAL PROCEDURES COORDINATION ACT.

[deferred]

#### ARTICLE 5. COASTAL MANAGEMENT CONSISTENCY DETERMINATIONS.

22 AAC 10.500. SINGLE DETERMINATION REQUIRED FOR CERTAIN PROJECTS. (a) For activities covered by secs. 510-540 of this chapter which require a coastal management consistency determination under AS 46.40.100(a), AS 46.40.200, 6 AAC 80.010(b), or 16 U.S.C. sec. 1456(c), one consistency determination will be made for that activity in accordance with secs. 510-540 of this chapter. The determination made under secs. 510-540 is conclusive to the extent of its coverage, but does not affect the jurisdiction of any agency over a proposed activity under its own statutes and regulations. Nothing in secs. 500-580 of this chapter may be construed as limiting local government jurisdiction over any activity.

(b) Notwithstanding (a) of this section, secs. 510-540 of this chapter do not insulate an activity from an otherwise required consistency review solely because that activity is a consequence of a previous, less specific decision. However, a consistency determination on a more specific consequential activity is bound by those decisions, findings and conclusions actually made at prior, less specific decision-making stages. Moreover, the scope of any consistency determination on a more specific activity is limited by the scope of the more specific permit proceeding.

(c) Notwithstanding (b) of this section, an agency making a consistency determination under secs. 510-540 of this chapter, may, in the course of a required permit proceeding conducted by that same agency for a more specific consequential activity, reappraise its prior determination on the basis of new information which was not available at the prior stage.

22 AAC 10.510. CONCLUSIVE CONSISTENCY DETERMINATIONS ON ACTIVITIES INVOLVING ENVIRONMENTAL IMPACT STATEMENTS AND ACTIVITIES OCCURRING ON THE OCS. When a direct federal activity or a federal permit or license necessitates preparation of an Environmental Impact Statement under 42 U.S.C. § 4332, the Office of the Governor, Division of Policy Development and Planning, will perform the consistency review for the activity, permit or license under 16 U.S.C. § 1456(c). The division will also conduct the determination for activities occurring on the Outer Continental Shelf adjacent to Alaska. Subject to secs. 500 and 580 of this chapter, no other consistency determination will be made for state or federal law purposes on the activity by a state agency.

22 AAC 10.520. CONCLUSIVE CONSISTENCY DETERMINATIONS INVOLVING DISPOSALS OF INTEREST IN STATE LANDS AND PLANS OF OPERATION. Except as provided in sec. 510 of this chapter, consistency determinations on disposals of an interest in state land will be performed by the Department of Natural Resources. That department will also conduct the consistency determination on activities authorized by a required plan of operations, and subsequent plan amendments. Subject to secs. 500 and 580 of this chapter, no other consistency determination for state or federal law purposes will be made on the activity by a state agency.

22 AAC 10.530. CONCLUSIVE CONSISTENCY DETERMINATIONS INVOLVING § 401 CERTIFICATION. Except as provided in secs. 510 and 520 of this chapter, when a federal permit is necessary for an activity, and state certification of the activity is provided for under Section 401 of the Clean Water Act (33 U.S.C. § 1341), the consistency determination for that activity will be performed by the Department of Environmental Conservation in the course of its certification procedure. Subject to secs. 500 and 580 of this chapter, no other consistency determination will be made for state or federal law purposes by a state agency on the certified activity.

22 AAC 10.540. CONCLUSIVE CONSISTENCY DETERMINATIONS INVOLVING DIRECT STATE AND FEDERAL ACTIVITIES. (a) Except as provided in secs. 520-530 of this chapter, consistency determinations on the following direct state and federal activities will be conducted by the division:

- (1) proposed administrative orders of the governor;
- (2) federal grant applications or applications for other forms of federal assistance if the proposal substantially involves more than one state agency; if the funds are destined for multiple recipients; or if there is no state agency administering the funds;
- (3) all funding and regulations arising from the authority of the federal Coastal Zone Management Act;
- (4) state plans, programs and studies developed by or affecting more than one state agency if no lead agency has been designated by statute or executive action;
- (5) federal activities for which there are no state permits or other approvals required at the current level of detail; and
- (6) other state actions when requested by the action-taking agency.

(b) Except as provided in secs. 510-530 of this chapter, consistency determinations for other direct state and federal activities will be made by the appropriate state agency.

22 AAC 10.550. CONSISTENCY DETERMINATIONS ON OTHER ACTIVITIES. (a) For activities not covered by secs. 510-540 of this chapter, consistency determinations will be made by state agencies in the course of otherwise required permit review, and by the division for the purposes of 15 C.F.R. § 930.

(b) Nothing in this section, or 6 AAC 80.010, may be construed as in any manner limiting the authority of a resource agency to issue general permits.

(c) Subject to approval of the Alaska Coastal Policy Council, agencies may, by regulation, determine which classes or types of actions or permits they administer may have a de minimis impact on the coastal zone, and for which a consistency determination will not be required.

22 AAC 10.560. AIR, LAND AND WATER QUALITY CONSISTENCY REVIEW. When those standards referenced in 6 AAC 80.140 have been or will be addressed for the activity by the Department of Environmental Conservation in a required permit or certification proceeding, those standards will not be a part of any consistency determination for that same activity conducted under this chapter.

22 AAC 10.570. PROCEDURE FOR CONSISTENCY DETERMINATIONS.

(a) When a consistency determination is integrated into an existing permitting process under secs. 510-550 of this chapter, that integration does not alter the procedures applicable to that permit, except as provided in this section.

(b) For the purposes of this section, and secs. 130 and 160(3) of this chapter, when a consistency determination is made under secs. 510-550 of this chapter, "resource agency" includes all state agency members of the Coastal Policy Council and any coastal resource district with an applicable and approved coastal management plan under AS 46.40;

(c) When a consistency determination is made in the course of a disposal of interest in state land under sec. 520 of this chapter:

(1) notice required under AS 38.05.305 and AS 38.05.345 will state that a consistency determination on the proposed disposal will be made, and will solicit comments or consultation on the issue of consistency within the time period provided pursuant to those statutes;

(2) sec. 130 of this chapter applies, except that the time for initiating the 21-day agency comment period under that section is governed by the policies of the Department of Natural Resources; and

(3) sec. 160 applies to that portion of the decision under AS 38.05.035(a)(14) which concerns the consistency of the proposed disposal.

(d) When a consistency determination is made by the division under sec. 510 or 550 of this chapter, the determination is a Class II permit proceeding.

(e) Whenever a consistency determination is made in the course of a Class I proceeding, the deciding agency, notwithstanding sec. 100 of this chapter, will;

(1) timely consult with other resource agencies on a selective and informal basis;

(2) comply with section 160(3) of this chapter;

and  
(3) if requested, serve a copy of the consistency determination, with a description of the activity, on the division.

(f) Subject to (c) and (d) of this section, consistency determinations on direct federal and state activities will be conducted according to Class I or II permit procedures as necessary review time warrants.

22 AAC 10.580. APPLICANT RESPONSIBILITY IN MULTIPLE PERMIT CASES. When an activity requires more than one permit, the applicant, in order to obtain a conclusive determination under secs. 510-540 of this chapter, should apply for the appropriate permit under those sections prior to or contemporaneous with application for any other necessary federal permit or license. If an applicant makes premature application for a federal permit or license other than one providing the appropriate forum under secs. 510-540 of this chapter, the division, under sec. 550 of this chapter, may be required to make a determination under 15 C.F.R. § 930.63 before the determination under secs. 510-540 of this chapter is possible. In that event, the division will request the applicant to immediately apply for the appropriate permit, and:

(1) if application is made sufficiently in advance to permit an agency decision under secs. 510-540 of this chapter within the time allowable under 15 C.F.R. § 930.63, defer to that determination; and

(2) if application is not made sufficiently in advance, in its discretion;

(A) proceed to make a consistency determination under sec. 550 of this chapter; or

(B) object to the proposal on the basis of insufficient information under 15 C.F.R. § 930.64(d).

#### ARTICLE 6. GENERAL APPEALS PROVISIONS.

22 AAC 10.600. CLASSES OF APPEALS. There are two classes of appeals from decisions on a Class I-II permit application. A Class A appeal is informal; a Class B appeal involves more formal adjudicatory procedures. The regulations of each resource agency specify which class of appeal may be taken from particular permit decisions.

22 AAC 10.610. VOLUNTARY RELINQUISHMENT OF RIGHT TO CLASS B APPEAL. (a) Even if an applicant is entitled to a Class B appeal, he may wish to take a Class A appeal in order to expedite the appellate process. The appellate officer will grant a request for a Class A appeal under this section if, at the time of filing a notice of appeal under sec. 620 of this chapter, the applicant serves an executed waiver of rights on a form provided by the agency.

(b) Conversion from a Class B to a Class A appeal is solely for the benefit of the applicant, and deprives the deciding officer of the same rights and opportunities relinquished by the applicant. The agency, on behalf of the deciding officer, would not consent to conversion under this section but for the execution of the waiver by the applicant, and the agency will be acting in express reliance on that waiver.

22 AAC 10.620. NOTICE OF APPEAL. (a) Within 15 days of service of an agency decision under sec. 60 of this chapter, or, for Class I permits, within 15 days of entry of the agency decision for persons not required to be served under sec. 60 of this chapter, a person may serve a notice of appeal upon the deciding agency and the applicant which must contain:

(1) the name, mailing address, and telephone number of the person making the request;

(2) the names and addresses of all persons adversely affected by the decision whom the requestor represents;

(3) a statement as to how the decision will injure the requestor; and

(4) a clear and concise statement of the material factual issues proposed for consideration on appeal.

(b) Where application was made solely for a permit amendment, the notice of appeal may not raise issues relating to the validity of the permit for which an amendment is sought, nor to unrelated terms and conditions of the permit for which no amendment has been sought.

22 AAC 10.630. STAY OF DECISION. (a) The agency's decision is not stayed during the pendency of the hearing. However, a requestor may, contemporaneous with service of his notice of appeal under sec. 620 of this chapter, serve a motion upon the appellate officer to stay the department's decision, or a portion of it, pending the hearing. The agency will then serve the request upon all other requestors, and the applicant. In reviewing a stay motion the appellate officer will consider

(1) the relative harm to the person requesting the stay, the applicant, and the public health and environment, from the granting or denial of a stay;

(2) the resources which would be committed during the pendency of the appeal if the stay were granted or denied; and

(3) the likelihood that the person requesting the stay will prevail on the merits.

(b) No stay will be granted of a denial of a permit application for either a new operation, or an operation which commenced after the effective date of the statute or regulation requiring a permit.

(c) Within 10 days after service of the stay petition under (a) of this section, any party opposing the stay may serve a response upon the appellate officer and all requestors.

(d) The agency will serve its decision on a stay motion within 10 days after the expiration of the deadline for a response under (c) of this section.

22 AAC 10.640. ACTION ON NOTICE OF APPEAL. (a) Within 10 days after service of a notice of appeal, the agency will serve its decision on the notice upon the requestor and the applicant. The agency will grant a request for an appeal if the request discloses that the requestor would be directly and adversely affected by the agency's decision; the requestor has raised a genuine issue of fact material to the decision; if a request for comment was published or a hearing was held on the application, the specific issues presented on appeal were raised in timely submitted comments or hearing testimony; and the requirements of sec. 620 of this chapter have otherwise been met. If a hearing request is granted for a person other than the applicant, the applicant is a party to the appeal.

(b) If the agency grants an adjudicatory hearing request for a Class B appeal, it will publish notice of the action in a newspaper of general circulation for the affected area, and will serve notice on all persons who were served with the decision under sec. 60 of this chapter. A person wanting to intervene in the proceedings may serve upon the agency and all parties a petition for intervention containing the information specified in sec. 620 of this chapter, within 10 days after publication of notice or service of notice under this section, whichever first occurs. Any party may serve an objection to the intervention petition within 10 days after service of the petition upon him. The agency will reach a decision on the intervention request within 10 days after the expiration of the period for serving an objection.

22 AAC 10.650. CONSOLIDATION. When more than one hearing request is granted, all requests will be joined in a single proceeding.

#### ARTICLE 7. CLASS A APPEALS.

22 AAC 10.700. WRITTEN ARGUMENT ON APPEAL. Within 15 days of service of notice granting his notice of appeal under sec. 640 of this chapter, the requestor shall serve his written arguments on the appellate office and all parties to the appeal.

22 AAC 10.710. SUMMARY ACTION. (a) When the applicant is a requestor, the appellate officer, in his discretion and under applicable standards, will affirm, modify or reverse the decision on the basis of the argument served under sec. 700 of this chapter. When the applicant is a respondent, the appellate officer, in his discretion, will affirm under this subsection.

(b) The appellate officer will require responsive written argument when action is not taken under (a) of this chapter.

(c) The appellate officer will serve notice of responsive argument under (b) of this section within 10 days of service of the requestor's argument under sec. 700 of this chapter.

(d) Argument allowed under this section must be served within 15 days of service of the notice under (c) of this section.

22 AAC 10.720. APPEARANCE BEFORE COMMISSIONER. (a) The appellate officer will serve notice of oral hearing on all parties within 10 days of timely service of allowable written argument under sec. 710 of this chapter if he determines that a hearing will materially aid his disposition of the appeal.

(b) The hearing will be held under procedures which the appellate officer determines are best suited for resolution of the issues and protection of the parties. The notice under (a) of this section will specify the procedures to be followed. The hearing will be held no sooner than 10 nor more than 20 days following service of notice under (a) of this section.

22 AAC 10.730. DECISION ON APPEAL. The appellate officer will serve his findings of fact and conclusions of law upon the parties within 30 days of timely service of argument under sec. 710 of this chapter, or within 30 days of the holding of a hearing under sec. 720 of this chapter.

#### ARTICLE 8. CLASS B APPEALS.

22 AAC 10.800. DISCOVERY. (a) Immediately after the agency determines that no additional parties will be added to the proceeding, it will serve notice on each requestor that, within 15 days, each requestor must serve upon each respondent

(1) a complete and concise summary of the issues and factual matters which the requestor will present at the hearing;

(2) the name, address, telephone number, and occupation of each witness whom the requestor intends to call at the hearing, and the purpose of his testimony; and

(3) the nature, location, and custodian of any real or documentary evidence which the requestor intends to introduce at the hearing, and the purpose of its introduction.

(b) Within 20 days after service of the matters specified in (a) of this section, each respondent must serve upon each requestor

(1) the name, address, telephone number, and occupation of each witness which the respondent intends to call at the hearing, and the purpose of his testimony; and

(2) the nature, location, and custodian of any real or documentary evidence which the respondent intends to introduce at the hearing, and the purpose of its introduction.

(c) When a party is both a requestor and a respondent, he must serve the matters under (a) of this section as to those issues for which he is a requestor, and must serve the matters under (b) of this section as to those issues for which he is a respondent.

22 AAC 10.810. PREHEARING CONFERENCE. (a) The appellate officer may direct the holding of a prehearing conference if he determines that a conference will substantially aid

resolution of the appeal. At least 10 days' notice of the conference will be given to all parties. The time and place of the conference will be set by the appellate officer, with due regard for the convenience of the parties.

(b) At the prehearing conference, the appellate officer may explore, and is empowered to make any appropriate order regarding

(1) the simplification, clarification, or limitation of the issues, the striking of immaterial issues, and the summary disposition of issues over which there is no genuine dispute;

(2) the admission of facts and the genuineness of documents, and stipulations with respect to facts and documents;

(3) objections to the introduction into evidence at the hearing of any written testimony, documents, papers, exhibits, or other submissions proposed by a party; however, the failure to raise an evidentiary objection at the conference does not preclude a party from raising the objection at the hearing;

(4) matters of which official notice will be taken;

(5) establishment of a schedule, including definite or tentative times relating to the progress of the hearing;

(6) the taking and introduction of depositions;

(7) the use of affidavits in place of oral testimony;

(8) accepting, on good cause shown, supplements to the witness and evidence lists provided under sec. 800 of this chapter (specifically including rebuttal evidence to matters submitted under sec. 800(b) of this chapter);

(9) the exclusion of unduly repetitive or irrelevant evidence; and

(10) any other matter which will expedite the hearing or aid disposition of the matter.

(c) The prehearing conference will be tape recorded.

(d) The appellate officer will prepare, and will serve upon all parties, within 10 days after holding the conference, a written prehearing order reciting the actions taken at the prehearing conference and setting out the schedule for the hearing. The order will include a written statement of the areas of factual agreement and disagreement and of the methods and procedures to be used in developing the evidence and the respective duties of the parties in connection therewith. The order will control the subsequent course of the hearing unless modified by the appellate officer for good cause shown.

22 AAC 10.820. APPELLATE OFFICER. (a) The appellate officer will be designated by the regulations of the agency hearing the appeal. The appellate officer must not have participated or advised in the decision being appealed, and must occupy a position of authority in the agency higher than that of any person participating in the decision being appealed.

(b) When the appeal is subject to the Administrative Procedures Act (AS 44.62.330 et. sec.), a hearing officer will be appointed under AS 44.62.350. The hearing officer will preside on any pre-hearing conference held under sec. 810 of this chapter and at the hearing under sec. 830 of this chapter; rule on the admission or exclusion of evidence; advise the agency on matters of law; and be present during post-hearing consideration of the appeal. The appellate officer will hear the appeal with the hearing officer and the appellate officer will decide the appeal.

(c) When the appeal is not subject to the Administrative Procedures Act, the appeal will be heard as well as decided by the appellate officer and the appellate officer is considered the hearing officer for the purposes of secs. 830 and 840 of this chapter.

(d) The deciding officer or his staff will be represented by the Department of Law. The Department of Law will not advise or represent the hearing or appellate officer. If, for appeals under (c) of this section, the appellate officer determines that he needs legal assistance, he will retain a hearing officer under AS 44.62.350 to perform or assist in those functions which the appellate officer finds appropriate.

22 AAC 10.830. HEARINGS. (a) The sequence of argument, examination, and summation must conform to any prehearing order. The appellate or hearing officer may question a witness and, in multiparty proceedings, may limit cross-examination to one party on each side if he is satisfied that the cross-examination by one party will adequately protect the other parties. Other parties may, however, engage in cross-examination as to matters not covered by previous cross-examination.

(b) Evidence rules are governed by AS 44.62.560.

(c) The burden of proof and of going forward with the evidence is on the requestor.

(d) No issue, testimony or real or documentary evidence may be introduced or advanced at the hearing which was not previously disclosed under sec. 800 or 810(b)(8) of this chapter. The hearing officer may waive this prohibition if the failure to previously disclose was due to

(1) surprise;  
(2) newly discovered evidence which by due diligence could not have previously been discovered and disclosed; or  
(3) fraud, misrepresentation, or other misconduct of an opposing party.

(e) The prohibition of (d) of this section does not apply to evidence offered solely to rebut or impeach matters first disclosed pursuant to sec. 810(b)(8) of this chapter.

22 AAC 10.840. CERTIFICATION OF RECORD. As soon as the hearing transcript has been prepared, the hearing officer shall certify the record of the hearing and provide notice of the certification to all parties. Except for good cause shown, the cost of transcribing the hearing must be borne by the requestor. Where there is more than one requestor, the hearing officer may apportion the costs.

22 AAC 10.850. FINDINGS AND BRIEFS. Within 10 days after notice of the certification of the record under sec. 840 of this chapter, a party may serve upon the appellate officer, and all parties, proposed findings of fact. The appellate officer, at the close of the hearing, will, in his discretion, also order the submission of briefs if he determines that briefing will substantially aid his resolution of the case. The proposed findings are intended only as an aid to the appellate officer, and a ruling on the acceptance or rejection of the proposed findings is not required.

22 AAC 10.860. DECISION. The appellate officer will serve his findings of fact and conclusions of law upon the parties within 30 days after notice of certification of the record under sec. 850 of this chapter.

#### ARTICLE 9. MISCELLANEOUS PROVISIONS.

22 AAC 10.900. SERVICE. (a) Any matter required to be served under this chapter may be served by personal delivery, or by registered or certified mail (return receipt requested). Additionally, any matter required to be served before a request for an appeal under sec. 620 of this chapter may be served by first-class mail or interagency mail.

(b) Upon the granting of a request for an appeal under sec 640 of this chapter, a copy of all matters subsequently served, and proof of service, must be mailed to the appellate officer, or to the commissioner if an appellate officer has not yet been appointed. Proof of service must be made by an affidavit of service.

(c) When a pleading or paper filed in a case discloses that a requestor or respondent is represented by counsel, service upon the requestor or respondent must be made upon his attorney.

(d) When mail is used for service, service occurs upon mailing for the purpose of the serving party's obligation, and upon receipt for the purpose of commencing time limits upon the receiving party.

22 AAC 10.910. TIME COMPUTATIONS. Time computations under this chapter will be made in accordance with AS 01.10.-080.

22 AAC 10.920. DEFINITIONS. As used in this chapter:

(1) "appellate officer" means the employee designated by the deciding agency to decide an appeal taken under this chapter;

(2) "commissioner" means the commissioner of the deciding agency or his designee. For the purpose of sec. 020(a)(1) and sec. 020(b) of this chapter, the only authorized designee is the deputy commissioner of the deciding agency;

(3) "completed application" means an application form provided by the agency which is fully completed and properly executed: is accompanied by all material required to be included by the regulations of the deciding agency: and is served in accordance with the deciding agency's regulations at a place identified as appropriate for service in those regulations;

(4) "deciding agency" means the resource agency from which the permit must be obtained;

(5) "deciding officer" means the employee designated by the deciding agency to make the permit decision under sec. 60 of this chapter;

(6) "division" means the Division of Policy Development and Planning, Office of the Governor;

(7) "great weight" means deference unless the assertion is contrary to the weight of fact or opinion in the administrative record;

(8) "permit" means a permit, license, certification, consistency determination, plan review or other authorization or approval issued as a written document which is required to be obtained from a resource agency before construction or operation of a project. The term does not include disposals of an interest in state land or water, but does include all authorizations and approvals, whether proprietary or regulatory, necessary to undertake a project under a previously conveyed property interest;

(9) "primary area of expertise" means that scientific or technical expertise primary and peculiar to a particular resource agency. However, no commenting agency has "primary expertise" for the purpose of this chapter on questions of balancing competing factors. That is a decision vested in the deciding agency. If no balancing of competing factors (including factors within the deciding agency's own primary area of expertise) is involved, the deciding agency must accord great weight to a resource agency's assessment of impacts on that resource. For example, if, under sec. 130 of this chapter, the Department of Environmental Conservation comments that a particular activity will have certain adverse water quality impacts, and that a certain mitigating measure would be appropriate, the deciding agency must accord great weight to the assessment of impact, but will not accord great weight to the recommended condition if deciding upon that condition turns upon a balance of other factors. The primary area of expertise of the Office of Coastal Management is interpreting the meaning of 6 AAC 80;

(10) "requestor" means a person requesting an appeal under sec. 620 of this chapter;

(11) "respondent" means a person defending the agency's decision; and

(12) "resource agency" includes the departments of Environmental Conservation, Natural Resources, and Fish and Game, and the Office of the Governor, Division of Policy Development and Planning.

6 AAC 80.900(20) is amended to read:

(20) "feasible and prudent" has the same meaning as in sec. 4(f) of the Department of Transportation Act of 1966, 49 U.S.C. § 1651(f);

6 AAC 80.010(b) is amended to read:

(b) Nothing in this chapter or in any district program displaces or diminishes the authority of any state agency or local government with respect to resources in the coastal area. Uses and activities conducted by state agencies in the coastal area must be consistent with the applicable district program and the standards contained in this chapter. In authorizing uses or activities in the coastal area under its statutory authority, the appropriate state agency under 22 AAC 10.510-550 shall grant authorization if, in addition to finding that the use or activity complies with the agency's statutes and regulations, the agency finds that the use of activity is consistent with the applicable district program and the standards contained in this chapter.

**PLEASE NOTE: THE PRECEDING PAGES WERE TREATED  
AS A UNIT IN THE ORIGINAL DOCUMENT.**

STATE OF ALASKA  
THE LEGISLATURE

POUCH Y - STATE CAPITOL  
JUNEAU, ALASKA 99811  
907-465-3800

LEGISLATIVE AFFAIRS AGENCY

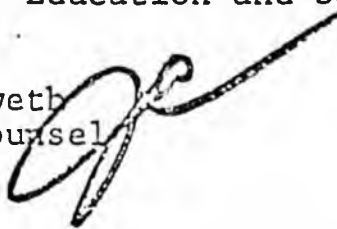
MEMORANDUM

April 4, 1980

SUBJECT: CSSB 269, relating to nuclear wastes

TO: Senator Glenn Hackney, Chairman  
Senate Health, Education and Social Services  
Committee

FROM: John B. Chenoweth  
Legislative Counsel



There was some confusion concerning instructions to complete the second redraft of this committee substitute. While the department's "position paper" wanted a ban only on "high level nuclear wastes" from nuclear power plants, your committee's actual request was limited to "high level nuclear wastes", presumably from any source. I do not know how to quantify "high level" with precision. Not wanting to tie to a figure expressed in terms of measurements that delight physicists and trouble legislators, I have suggested language in the draft that leaves the determination (other than as to wastes from nuclear plants) to an administrative agency. I note that, at 18 AAC 85, the Department of Environmental Conservation has already defined permissible disposable nuclear wastes.

The bill draft also makes clear that the prohibition is not intended to preclude storage and disposal of quantities of nuclear wastes generally used in education, research and medicine.

JBC:ljb

Enclosure

# STATE OF ALASKA

DEPT. OF ENVIRONMENTAL CONSERVATION

JAY S. HAMMOND, GOVERNOR

POUCH Q - JUNEAU 99811

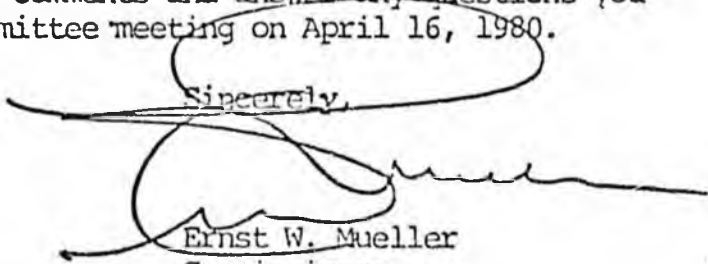
April 15, 1980

The Honorable Glenn Hackney  
Chairman  
Senate Health & Social  
Services Committee  
Alaska State Senate  
Pouch V  
Juneau, Alaska 99811

Dear Senator Hackney:

The Alaska Department of Environmental Conservation would like to submit the following comments and recommendations on SB 269 concerning the disposal of nuclear wastes in Alaska. We support this bill and the several minor changes which have been recommended. We would be more than willing to present these comments and answer any questions you might have at the 3:00 pm Committee meeting on April 16, 1980.

Sincerely,



Ernst W. Mueller  
Commissioner

Enclosure

ALASKA DEPARTMENT OF ENVIRONMENTAL CONSERVATION

REVIEW OF SB-269  
AN ACT PROHIBITING THE DISPOSAL OF NUCLEAR WASTE MATERIAL

Submitted to the  
Senate Health, Education and Social Services Committee

SB 269 makes changes in the current Alaska Statutes 18.45.025 FACILITIES SITING PERMIT REQUIRED, to prohibit the siting of any facilities which would allow the storage or disposal of radioactive waste materials within the State of Alaska. The Department strongly supports this legislation, particularly as it relates to the disposal of highly radioactive waste materials from nuclear power plants.

Wastes from nuclear power generating facilities require extremely long storage times before their radioactivity is reduced to safe levels. These wastes are difficult to contain in a safe manner, require extremely expensive containment technology which up to now has not proven reliable for long-term storage. While wastes from existing plants in other states will require some form of disposal method, Alaska should not become a dumping ground for these wastes. SB 267 would prohibit this from occurring, except in the unlikely event of federal preemption.

In supporting this legislation, we understand that a change has been or is going to be made in the legislation to expressly prohibit only the disposal of high level radioactive wastes from nuclear power plants. We support this change, because the disposal of small amounts of low level radioactive wastes generated from medical, laboratory and industrial facilities can be accomplished without creating a hazard to public health and the environment. Many of these low-level wastes cause no danger to the public if they are disposed in a safe and environmentally sound manner. Therefore, the existing authority to establish regulations under AS 46.03.250 should be adequate to assure proper handling and safe disposal of the low-level radioactive waste materials presently being generated in Alaska.

We thank you for the opportunity to comment on this legislation.

# STATE OF ALASKA

JAY S. HAMMOND, Governor

## DEPT. OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

POUCH H-06-JUNEAU 99811

POUCH H-06-JUNEAU-9980K

April 15, 1980

The Honorable Glenn Hackney  
Chairman  
Health, Education  
and Social Services Committee  
Alaska State Senate  
Pouch 'V', State Capitol Building  
Juneau, Alaska 99811

Document # 79-80

Dear Senator Hackney:

Sid Heidersdorf, Radiological Physicist for the Division of Public Health, is out of town this week and therefore unable to testify at the Wednesday hearing on CSSE 269. He has asked that I convey his concerns regarding this bill to you for consideration by your committee.

We are pleased to note that the Committee Substitute for Senate Bill 269 allows the storage and disposal of nuclear waste resulting from medicine, scientific research and education. We have a few additional concerns we feel should be weighed by the committee in their deliberations on this bill.

### Consideration No. 1

Section 18.45.025 removes nuclear waste disposal facilities from the permit requirements listing. At some time in the future, if disposal requirements from medical, scientific and educational sources become great enough, a waste disposal facility may be required within the state for wastes generated from these sources. In that event, any such facility should be required to receive a permit from the Department of Environmental Conservation.

### Consideration No. 2

Section 18.45.027 prohibits the transportation of nuclear waste material in the state except for purposes of disposal outside the state. It is suggested that the prohibition should be directed against high level nuclear waste materials since there may be necessity to transport low level wastes from medical, scientific and educational sources. The State has regulations covering the transportation of nuclear materials (18 AAC 85.320).

### Consideration No. 3

Section 18.45.029(b)(1)(B) seems to add to the potential for confusion

over the term "high level nuclear material" rather than to clarify the definition as intended. For example, low level wastes from medical, research and educational uses, when improperly stored or disposed of, could be "material of a kind or quantity which .... would constitute a threat to the health or safety of the public....". Safe disposal of radioactive wastes is already covered by regulation in 18 AAC 85.270 - 310.

Recommendations

1. In Section 18.45.025, retain the requirement for a permit for the siting of a nuclear waste disposal facility.
2. In Section 18.45.029, delete subpart (1) (B) since it does not appear to add clarity to the definition of "high level nuclear material" and rephrase 18.45.029 (1) (A) to read "nuclear waste material produced by nuclear power plants and nuclear fuel processing facilities".
3. A preferable alternative to Recommendations 1 and 2 is to delete Section 18.45.029 in its entirety and rephrase Section 18.45.027 as follows:

Section 18.45.027. TRANSPORTATION, STORAGE AND DISPOSAL OF NUCLEAR WASTE MATERIAL. The transportation, except for purposes of disposal outside the state, storage and disposal of high level nuclear waste material from nuclear power plants or nuclear fuel processing facilities is prohibited.

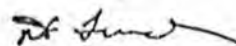
Such phrasing would be consistent with the continued use of low level nuclear materials for medical, scientific or educational purposes and would eliminate the need for defining "high level nuclear waste".

Department's Position

The Department of Health and Social Services is neutral on CSSB No. 269 if these recommendations are incorporated in the final draft.

Thank you for the opportunity to present Mr. Heidersdorf's testimony to you in this letter. He will be back in his office Monday, April 21st and will be able to provide you or your committee members with any additional information you may require.

Sincerely,



Dean F. Tirador, M.D.  
Director  
Division of Public Health

DFT/nd

POSITION PAPER

SENATE BILL NO. 269

"An Act prohibiting the disposal of nuclear waste material."

Senate Bill No. 269 prohibits the storage and disposal of nuclear waste material in Alaska. This prohibition is without qualification as to quantity, origin, and kind.

Alaska has approximately 35 licensed users of radioactive materials. Since Alaska is not an Agreement State under the Atomic Energy Act, the Department of Health and Social Services does not have jurisdiction over these sources. They are licensed and controlled by the United States Nuclear Regulatory Commission.

Presently, nuclear waste material in some form or other is either stored and/or disposed of in Alaska. It is estimated that from eight to ten of the facilities licensed in the State by the Nuclear Regulatory Commission use unsealed sources which require some storage and disposal following use.

Unsealed sources, as differentiated from sealed sources, are those not encapsulated in a container. Unsealed sources, kept in openable bottles or other containers, are necessary in research and nuclear medicine so they can be used in various laboratory procedures or in medical practice by ingestion, inhalation or injection. This use results in various kinds of radioactive wastes. Facilities presently using unsealed sources are four hospitals located in Juneau, Anchorage, and Fairbanks. Unsealed sources are also frequently used in private, Federal, and State research and/or educational facilities carrying out activities such as those conducted by the NOAA Auke Bay Fisheries Laboratory, U.S. Geological Survey, and the University of Alaska Institutes of Marine Science and Arctic Biology. Some of these unsealed sources may also be used in industrial applications--for example, activities related to the oil industry.

Radioactive wastes are in the form of liquids, contaminated laboratory articles, biological samples, and such items as towels and clothing. Generally these would be stored in liquid-tight barrels, on site, in an area with limited and controlled access. Storage is necessary until materials can be shipped to a licensed radioactive waste disposal site, such as the one in Rickland, Washington. Alaska does not have an approved waste disposal site, and the present low volume of such waste has not yet caused a problem for users in Alaska.

Presently, hospitals in Alaska store radioactive waste until it has decayed to very low levels (near background). The material is then either incinerated or disposed of in sanitary sewerage systems according to regulations established by the Nuclear Regulatory Commission.

This Bill, if passed as presently worded, will eliminate the use of unsealed radioactive sources in Alaska--a situation which will have a harmful impact on the delivery of medical services and research activities within the State. Accordingly, the following changes in wording are recommended:

Line 12: Leave in the phrase "OR NUCLEAR WASTE DISPOSAL FACILITY".

Lines 26-28: Section 18.45.027. DISPOSAL OF NUCLEAR WASTE MATERIAL. The disposal of high levels of nuclear waste material in the State from nuclear power plants is prohibited.

The changes recommended above are suggested only to protect the use of radioactive materials in nuclear medicine facilities, research, and education. It is recognized that the prohibition of the disposal of high level waste from nuclear power plants may directly affect future State policy and the interest of other State agencies. This matter of State policy regarding disposal of high level waste has ramifications far beyond the authority of this Department, and consequently is not addressed by this position paper.

With the above recommended changes, the Department of Health and Social Services takes a neutral stand on Senate Bill No. 269.

Recommended by:

Dean F. Tirador  
Dean F. Tirador, M.D.  
Director, Division  
of Public Health

Date:

17 Nov 80

Approved by:

Helen D. Beirne  
Helen D. Beirne  
Commissioner

Date:

13/20/80

DEPARTMENT OF HEALTH & SOCIAL SERVICES

# STATE OF ALASKA

DEPT. OF ENVIRONMENTAL CONSERVATION

*Sally*  
MAR 18 1980

JAY S. HILTON, GOVERNOR

POUCH 0 -- JUNEAU 99811

The Honorable J. M. Kerttula  
Senator  
Alaska State Senate  
Pouch V  
Juneau, Alaska 99811

Dear Senator Kerttula:

The Department recently completed an analysis of House Bill 511 relating to the disposal of hazardous wastes. Because of your interest in hazardous wastes, we have enclosed a copy for your information. The bill will need some changes if we are to develop a reasonable hazardous waste disposal program, and our analysis makes recommendations on how that might occur.

There have been indications in the past several weeks that the House Resources Committee expects to schedule this bill for hearings. We are working with committee's staff in drafting a substitute bill in preparation for those hearings. This should occur soon, and we will keep you informed on this effort.

Sincerely yours,

*C. Deming Cowles*

C. Deming Cowles  
Deputy Commissioner

ALASKA DEPARTMENT OF ENVIRONMENTAL CONSERVATION

ANALYSIS OF HB 511, AN ACT  
RELATING TO THE DISPOSAL OF HAZARDOUS WASTE

A. SUMMARY OF BILL

The department interprets the intent of HB 511 to mean that the Legislature wishes to protect the lands and people of the state from the potential dangers of hazardous waste disposal rather than the use or generation of hazardous materials. The bill delegates to the Alaska Department of Environmental Conservation (ADEC) the power to adopt regulations for the safe, proper disposal of hazardous waste so as to protect the health, safety and welfare of the public and the quality of the environment. However, it grants this power with reservations, since the bill also prohibits the disposal of hazardous waste in Alaska unless processing renders the wastes harmless.

B. ANALYSIS

The department's interpretation of HB 511 takes into account the numerous examples of illness, death, and mutations throughout the continental United States that have been traced directly to disposal sites for hazardous wastes. The department further assumes that the intent is not to halt the use or generation of hazardous substances except in certain instances, because such a ban would hinder economic development. As the Alaska economy diversifies the possibility exists that more industries and corporations which generate hazardous waste will be attracted to and wish to locate in the state.

1. Positive Aspects of the Bill

HB 511 is the first attempt to grant specific Legislative authority to handle and manage hazardous wastes in Alaska. Currently the Alaska Statutes authorize ADEC to adopt regulations concerning collection and disposal of garbage, refuse, and other discarded solid waste materials from industrial, commercial, agricultural and community activities or operations. It is under this broad statutory authority that ADEC has assumed responsibility for establishing a hazardous waste management program. Specific legislative authorization would, however, clarify the state's role and responsibility in hazardous waste management.

Specifically, the following aspects of the bill are necessary for a coordinated hazardous waste management program.

- (a) Section 20 authorizes the department to adopt regulations for the disposal of hazardous wastes. This power, however, is limited by Section 10, which bans all disposal of hazardous waste in the state. The materials considered below are examples of wastes which the department presumes could be regulated under the bill.

While uranium is not presently being mined in Alaska, at least one earlier mine and continuing explorations present evidence that Alaska has the potential for large-scale uranium mining. The large amounts of waste rock and overburden contain potentially hazardous radioactive materials, either directly through radon escape or indirectly through leachate. From a practical standpoint, this overburden would have to remain in Alaska.

Waste oil is considered by the Environmental Protection Agency to be hazardous. In fact, it is singled out for special treatment because the use of waste oils for dust suppression or incineration has been known to cause serious environmental effects. However, waste oil is heavily utilized as a dust suppressant on roads throughout Alaska. The only State requirement to its use in such a manner is that the user obtain a department permit under 18 AAC 75.010-060. The use of waste oil in this manner may be considered illegal by EPA once their final hazardous waste regulations are promulgated this Spring and Summer.

Because of Alaska's increasing involvement in petroleum production, the number of oil spills has been increasing yearly. In 1979 alone there were four major oil spills - the M/V Lee Wang Zin near Ketchikan, the M/V Ryuyu Maru off the Pribiloffs, the Cordova Chugach Cannery, and the Atigun Pass spill. Oil spilled from these four incidents alone totalled over 632,000 gallons. Much of this oil went directly into the environment; the remainder has or is being cleaned up. While EPA does not consider oily wastes as hazardous, Alaska does consider them special enough to warrant specific legislation, AS 30.25.120.(c). Also, Section 30.25.061(c) of HB 205, "An Act Relating to the Prevention and Control of Oil Pollution" deals with the disposal of oil spill clean-up materials. When not handled correctly these wastes pose a hazard for individuals and the environment. Bulky, difficult and expensive to transport, and a cause of localized air pollution if burned and water pollution if leachate forms, oily wastes cannot be shipped out of state nor simply left in a stored condition with no future plan for disposal.

In the above situations the conditions under which disposal will be allowed must be clarified. If section 10 were deleted or modified, Section 20 would give the department the authority to clarify these conditions and would then provide the sound basis for a management program geared to Alaskan conditions.

- (b) If Section 10 were deleted or modified, Section 20 would be the start of obtaining the required authority should the department decide that assumption of the federally-mandated hazardous waste program is in the best interest of the state.

In 1976 the Resource Conservation and Recovery Act (RCRA) was passed by Congress. One of the main goals of the Act was prevention of pollution caused by the disposal of hazardous wastes, the primary means for achievement being a manifest system. The manifest, similar to a bill of lading and signed by all persons in contact with the wastes, would be filed with the responsible state or federal agency. In this way a waste could be traced from generation to final disposal.

Congress stressed that states should assume responsibility for their own hazardous waste management program. Funds were appropriated for hazardous waste inventories, economic analyses of additional state resources needed under program adoption, analyses of the effect on industries, and planning. If a state did not assume responsibility, EPA would be required to manage hazardous wastes in that state.

Alaska is considering whether or not to assume all or part of the RCRA-mandated program or allow the Environmental Protection Agency to assume responsibility. Some of the points to consider are additional staff and paperwork necessary for program implementation, need for the State to have control over these wastes versus leaving control in federal hands, and the economic feasibility and preferences of industrial generators regarding state or federal jurisdiction. While federal money is available for program planning and start-up, the program must be completely state-funded within a few years. The department plans to make its decision in Fall, 1980.

While the authority given this department in HB 511 would probably be sufficient for interim authorization, full authorization by EPA will be dependent on the passage of complete legislative program authority as well as numerous requirements promulgated as regulations. Not only would a section on the state's authority to write regulations for specified aspects of hazardous waste management be needed, the bill should be changed to reflect the shortcomings and considerations discussed below.

## 2. Shortcomings of the Bill

The bill as written has several deficiencies;

- a. Sections 10 and 20 are conflicting. Whereas Section 10 prohibits disposal of hazardous waste in Alaska, Section 20 authorizes ADEC to write regulations for the safe disposal of hazardous waste. Since some hazardous wastes may need disposal instate, the Legislature should remove the conflict.

- b. The bill defines hazardous waste so broadly that it is vague. The definition of hazardous wastes, taken from the Resource Conservation and Recovery Act, is adequate, however, RCRA further authorizes the Environmental Protection Agency to refine the definition by listing hazardous wastes. While the department could use Sec. 20 to identify hazardous wastes, the bill does not specifically give the department that authority.
- c. Banning hazardous waste disposal alone will not guarantee protection. Transportation and storage of hazardous wastes are potentially as damaging as disposal. Even should Section 10 stand as written, hazardous wastes will need to be stored prior to processing or transporting. Again, the department could use Sec. 20 to guarantee proper treatment, storage, and transportation methods, but the bill does not explicitly grant this authority.
- d. Section 30 singles out corporations for special punishment for a violation of any hazardous waste requirement. However, the potential of contamination from improper hazardous waste handling is as great from individuals as from corporations. Penalties should either come under existing penalty provisions in AS 46.03 or be generalized so as to cover everyone.
- e. A slight point in Section 10 is that once a hazardous waste is processed to remove its harmful qualities, it is no longer hazardous. Therefore this qualifying phrase in the section is unnecessary.

### 3. Considerations

- a. At this time the status of hazardous waste in Alaska is unknown. The department recently began an inventory of hazardous waste types and amounts, generators, disposal sites, transporters, processors, and handling methods in order to determine what controls Alaska should have. This would include evaluating whether Alaska needs a disposal site and what alternatives are available for disposal of hazardous wastes. Once these results are available the Legislature will be in a position to know what legislation would protect the people and lands of the State.
- b. Many states are reacting to improper and unsafe hazardous waste disposal practices by prohibiting all disposal or by prohibiting disposal of out-of-state generated hazardous wastes. As the Alaskan economy diversifies, there will be the probability of attracting more industries and corporations that potentially generate hazardous waste. The Legislature should consider the possibility that Washington, which is the destination of most Alaskan transportable hazardous wastes, might not accept Alaskan hazardous waste in the future.

- c. The term "processed" is undefined; its definition will clarify the distinction between processing or treatment and disposal.

### C. RECOMMENDATIONS

Hazardous waste generation is often a necessary part of industrial development. Since economic diversification is a prime goal of the state, limiting or banning the disposal of hazardous waste could limit the number and types of industries wishing to locate in Alaska.

Even with limited industrial activity, however, a total ban on hazardous waste disposal would be inappropriate. Hazardous wastes are generated by medical facilities, by automobiles and other vehicles, by utilities and other facilities. However, the state must guarantee that when such wastes are generated that disposal and storage does not threaten or harm its people or environment. To do this HB 511 should be modified to take into account why and how hazardous wastes are generated and by whom.

As currently drafted, House Bill-511 would modify Alaska Statutes relating to the Department of Health and Social Services. Because the intent of this legislation is for the Department of Environmental Conservation to carry out hazardous wastes control efforts, we recommend that this proposed legislation be integrated into Alaska Statutes 46.03, which relates to the Department of Environmental as follows:

1. AS 46.03.020(10) be amended to add the following

(I) "Proper handling, transportation, treatment, storage, disposal, and control of hazardous wastes from the time of initial generation to final disposition."

2. The title of Article 6 be amended to read as follows:

"Article 6. Pesticide and hazardous solid waste control"

3. A new section AS 46.03.340 be added as follows:

"46.03.340. HAZARDOUS WASTE CLASSIFICATION, REPORTING. (a) The department shall classify hazardous wastes and their sources. Classifications made under this subsection may be for the state as a whole or to substate areas.

(b) the department may require a person generating, handling, or possessing hazardous solid wastes to submit reports containing information concerning location, amounts, and types of hazardous wastes.

4. A new section AS 46.03.350 is added to read as follows:

"46.03.350. HAZARDOUS SOLID WASTE REGULATIONS. The department shall adopt hazardous waste control regulations to provide for the disposal of hazardous wastes to protect the public health, livestock, wildlife, and the environment from any adverse effects. Such regulations may include requirements

for the handling, treatment, storage, and disposal of hazardous wastes, containerization, labeling and reporting."

5. AS 46.03.026 DEFINITIONS be amended to add the following:

( ) "Generation" means the act or process of producing hazardous waste.

( ) "Hazardous Waste" means a waste or combination of wastes which because of its quantity, concentration, or physical, chemical, or infectious characteristics may cause or significantly contribute to an increase in mortality or increase in serious, irreversable, or incapacitating reversible illness or propose a substantial present or potential hazard to human health or environment when improperly disposed."



Official Business

# Alaska State Legislature

Senate

Committee on Judiciary

Pouch V  
State Capitol  
Juneau, Alaska 99811

## MEMORANDUM

DATE: February 2, 1981

TO: Senate Judiciary Members

FROM: Kevin K. Bruce, Committee Aid

RE: SB 29

Please find enclosed the following material for hearings on SB 29, "An Act relating to nuclear materials":

- A.) SB 29
- B.) Amendments by Senate Resources Committee
- C.) Testimony by Department of Environmental Conservation on SB 29
- D.) Background material on SB 269 and HB 511, introduced last legislature.

STATE of Alaska et al., Appellants,  
and  
Cook Inlet Region, Inc., Appellant  
by Intervention.

v.

J. R. LEWIS and Harold H. Galliett, Jr.,  
Citizens and Taxpayers of the State of  
Alaska, Appellees.

No. 3039.

Supreme Court of Alaska.

Jan. 18, 1977.

Suit was instituted challenging constitutionality of a three-way exchange of land between the State of Alaska, the United States, and a regional native corporation. The Superior Court, Third Judicial District, Anchorage, C. J. Occhipinti, J., entered judgment declaring statute authorizing exchange unconstitutional and issued an injunction, and defendants appealed. The Supreme Court, Boochever, C. J., held that there was no provision in the Constitution against alienation of mineral rights that operates to preclude a land exchange pursuant to an agreement whereby the State will relinquish certain lands, including the subsurface minerals therein, to the United States in order to augment the federal holdings from which regional native corporations will obtain their aboriginal entitlements and, hence, legislative approval of exchange is sufficient once Congress consents to lifting restrictions imposed against alienation of mineral rights; further, authorizing statute is a general act, addressing a matter which is unique, but of state-wide concern, and is not invalid on ground that it weighs provisions of prior acts restricting State's right to alienate minerals and authorizing exchanges of land with native corporations for equal value, and statute is designed to facilitate state-wide land use management and to resolve a host of pressing legal issues and, as such, is not violative of constitutional prohibition on local and special legislation.

Injunction vacated, and declaratory judgment reversed.

Rabinowitz, J., dissented in part and filed an opinion in which Erwin, J., joined.

Burke, J., dissented in part and filed an opinion.

1. Constitutional Law  $\Leftrightarrow$  42.3(2)

Plaintiffs, who claimed that three-way exchange of land between State of Alaska, United States government, and regional corporation organized under Alaska Native Claims Settlement Act would result in losses to state treasury and taxpayers of vast sums of money, who sought to protect mineral resources in land originally selected from federal government under Statehood Act, and who as citizens and taxpayers were in a better position than governor and Attorney General to complain of exchange, had a sufficient personal stake in outcome of controversy to guarantee "the adversity which is fundamental to judicial proceedings" and had standing to bring suit challenging constitutionality of exchange. Laws 1976, c. 19; AS 38.05.125, 38.95.060; Rules of Appellate Procedure, rule 9(e); Const. art. 2, § 19; art. 8, § 9; Alaska Statehood Act, § 6(i), 48 U.S.C.A. preceding section 21; Alaska Native Claims Settlement Act § 22(f), 43 U.S.C.A. § 1621(f).

2. Constitutional Law  $\Leftrightarrow$  12

Statutes  $\Leftrightarrow$  81(1)

In construing a legislative act, a court need only look to the intent of the legislative members who enacted it, but in construing a constitutional provision, which must be ratified by the voters, it is also necessary to look to the meaning that the voters would have placed on the provision.

3. Mines and Minerals  $\Leftrightarrow$  4

Provisions of Constitution, rather than placing restraints on alienation of mineral rights, merely leave decision as to whether to require such reservations to Congress and State's legislature and, thus, impose no impediment to an exchange of land authorized by Congress and state legislature even though exchange involves a conveyance of

See complete doc. in Alaska Reporter

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B

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Official Business

# Alaska State Legislature

Senate

Judiciary Committee

Pouch V  
State Capitol  
Juneau, Alaska 99811

## MEMORANDUM

TO: File  
FROM: Oleta Simmons  
DATE: April 5, 1981  
SUBJECT: SB 41

The following individual would like to be informed of the next committee hearing on SB 41:

Susan Miller  
Alaska Court System  
303 K Street  
Anchorage, Alaska 99501

(264-0553)



# Alaska State Legislature

Senate

Judiciary Committee

Official Business

Pouch V  
State Capitol  
Juneau, Alaska 99811

March 30, 1981

David Cates, Ph.D.  
Alaska Native Health Board  
1689 C Street, Suite 230  
Anchorage, Alaska 99501

Dear Dr. Cates:

Thank you for your interest in SB 41.

Several members of the Committee feel that, although comparatively few cases have been uncovered by this statute, it acts as a screening device for individuals planning to marry, and may induce someone to seek medical attention.

Additionally, the Committee feels that the fiscal considerations are minor when balanced against the agony some persons may be spared by the test.

Again, I appreciate your expressing your views on this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Pat".

Patrick M. Rodey  
Chairman

PMR/ods

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MAR 23 1981

MSG 81-00009225 PRTY 1 03/20/81 17:04:02 ORIG: LA00 IN= 0020 OUT= 0087  
FROM: ROBERTA TO: JUNO INFO  
TARGET: LJH2 SUBJ: POMS PAGE 0001

TO: SENATOR PAT RODEY, CH. JUDICIARY COMMITTEE

FROM: DAVID E. CATES, PHD., AK NATIVE HEALTH BOARD 1689 C STREET, SUITE 230:  
276-8989

THE ALASKA NATIVE HEALTH BOARD HAS RESOLVED ITS SUPPORT FOR PASSAGE OF SB 41 AND URGES YOUR COMMITTEE'S APPROVAL. IF THERE ARE REASONS THAT ARE CAUSING ITS HOLD UP MAY WE PLEASE BE ADVISED SO THAT WE MAY SPECIFICALLY ADDRESS THEM?

T



# Alaska State Legislature

## Senate

### Judiciary Committee

Official Business

Pouch V  
State Capitol  
Juneau, Alaska 99811

April 23, 1981

Ms. Barbara Hoffmann  
Executive Director  
Alaska Council on Prevention  
of Alcohol and Drug Abuse  
7521 Old Seward Highway  
Suite A  
Anchorage, Alaska 99502

Dear Ms. Hoffmann:

Thank you for your comments in support of HB 41, an act providing mandatory coverage of drug and alcohol treatment for State employees.

This piece of legislation is scheduled to come before the House for vote on Friday, April 24, and its supporters are confident of its passage.

I will make every effort to ensure the passage of HB 41 when it reaches the Senate floor for vote.

Again, I appreciate your sharing your views.

Sincerely,

A handwritten signature in cursive script, appearing to read "Pat".

Senator Patrick M. Rodey  
Chairman

PMR/ods

# Alaska Council

ON PREVENTION OF ALCOHOL AND DRUG ABUSE

7521 Old Seward Hwy., Suite A  
Anchorage, Alaska 99502  
(907) 349-6602

April 7, 1981

RECEIVED

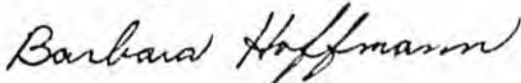
APR 09 1981

Dear Senator:

The Alaska Council would like to go on record as being in support of HB-41, which would provide mandatory coverage of drug and alcohol treatment for State employees. It would also provide a sliding fee schedule for moderate income employees.

We believe that early intervention is the best way to combat these problems and, therefore, heartily endorse HB-41.

Sincerely,



Barbara Hoffmann  
Executive Director

BH/SII/vab

Submitted by STEVEN ROSE  
M.D.

# OBSTETRICS and GYNECOLOGY *Journal of*

THE AMERICAN COLLEGE OF OBSTETRICIANS and GYNECOLOGISTS

Volume 52

July 1978

Number 1

## The Management of Rh-Isoimmunization

JOHN M. BOWMAN, MD

The Rh-isoimmunized woman can only be identified through routine blood grouping and antibody screening of all pregnant women at their first prenatal visits in all pregnancies. Rh antibody titrations at regular intervals must then be carried out. If there is a preceding history of stillbirth or a baby requiring exchange transfusion, or failing that, an Rh antibody titer placing the fetus at risk (1:16 in albumin or higher in the Winnipeg Rh Laboratory), amniocentesis and spectrophotometric examination of the amniotic fluid are indicated as early as 20<sup>th</sup> weeks' gestation. Serial amniotic fluid optical density ( $\Delta OD_{410}$ ) measurements by the Liley method are 95% accurate in predicting severity of fetal erythroblastosis and only 2 to 3% life threateningly inaccurate. If a single  $\Delta OD_{410}$  reading reaches or exceeds 0.400 or serial readings rise into the upper 75 to 80% of Zone 2, prompt fetal transfusion is indicated. Waiting until the  $\Delta OD_{410}$  measurement rises into Zone 3 is frequently associated with the presence of hydrops. Survival rates when fetal transfusions are required are 7% overall if the initial transfusion can be delayed until 26 weeks' gestation, 59% if the initial transfusion is necessary before 26 weeks' gestation, and 42% if initial transfusion is required between 21<sup>st</sup> and 23 weeks' gestation. Fetal transfusion should be undertaken if the fetus has gross ascites (hydrops). Survival rates are 21% if ascites is encountered at the first transfusion, 76% if ascites is not encountered until the second transfusion, and 78% if no ascites is found at any time. Optimal management of the fetus doomed to become hydropic unless delivered early or subjected to fetal transfusion can only be carried out in a tertiary level perinatal center with a fully developed intensive care neonatology program. With such management, perinatal mortality from Rh erythroblastosis has been reduced from 14.3 to 1.5%.

**T**REMENDOUS STRIDES have been made in the management of Rh-isoimmunization in the past 2 decades. With the advent of an effective means of prevention of Rh-isoimmunization the obstetrician will see very few Rh-isoimmunized pregnant women and his expertise in

the management of the problem in all of its aspects will diminish. The present review concerns itself with advances in the management of Rh-isoimmunization, particularly the prediction of severity of disease and its modification by early delivery or early delivery combined with intrauterine transfusion. The material discussed comes predominantly from the Rh Laboratory of the University of Manitoba and the Winnipeg Health Sciences Centre. The laboratory, founded in 1944, has been the sole provider of laboratory and clinical management services for Rh-negative pregnant women derived from a population base in excess of 1 million.

### HISTORY

Following the discovery of the Rh blood group system by Landsteiner and Wiener<sup>1</sup> in 1940 and the demonstration of its relationship to transfusion reactions in the mother and erythroblastosis in the fetus by Levine, Katzin, and Burnham<sup>2</sup> in 1941, the pathogenesis of isoimmunization and of erythroblastosis fetalis was placed on a firm footing. However, the perinatal mortality from erythroblastosis fetalis remained about 40 to 50% until Wallerstein introduced the technique of exchange transfusion in 1945.<sup>3</sup> The use of exchange transfusion halved the perinatal mortality rate, theoretically preventing all deaths and brain damage from kernicterus but doing nothing for the 20 to 25% of erythroblastic infants doomed to die of hydrops fetalis before term.

### RESIDUAL PROBLEMS IN MANAGEMENT OF RH-ISOIMMUNIZATION

The problems remaining since 1945 have been 1) Identifying the erythroblastic infant destined to become hydropic *in utero* before he becomes hydropic; 2) Determining when hydrops is going to occur; 3) Taking steps to prevent hydrops from developing; and 4) Delaying delivery until there is a reasonable chance of infant

From the Department of Pediatrics and the Rh Laboratory at the University of Manitoba and the Health Sciences Centre, Winnipeg, Manitoba, Canada.

Submitted for publication February 1, 1978.

survival. In this context it should be noted that half the fetuses doomed to become hydropic will become hydropic before 34 weeks' gestation (some as early as 22 weeks' gestation), the remaining half will become hydropic between 34 and 40 weeks' gestation.

The division of isoimmunized pregnancies in which fetuses will become hydropic into the two groups (hydropic before and after 34 weeks' gestation) is related to differences in management between the two. In the pre-fetal transfusion era, (1952 to 1963) approximate survival rates of severely erythroblastotic nonhydropic infants delivered prematurely in Winnipeg were as follows: 65% at 32, 80% at 33, 88% at 34, 94% at 35, and 96% at 36 weeks' gestation. Although the development of highly sophisticated perinatal treatment units in the past 10 to 12 years may have improved survival rates, the above figures have been useful in deciding, in the face of impending hydrops, what treatment measures should be taken—fetal transfusion or immediate early delivery. Although a 35% risk of death following delivery at 32 weeks' gestation was entirely acceptable when the alternative was death from hydrops *in utero*, it is no longer acceptable since fetal transfusion at 32 weeks' gestation carries with it a lower risk. Conversely, since initial fetal transfusion carries with it about a 10% risk, the 12% risk of delivery at 34 weeks' gestation may be acceptable.

#### DETERMINATION OF THE MOTHER AT RISK OF ISOIMMUNIZATION

It is self evident that unless the obstetrician knows the Rh and isoimmunization status of his pregnant patients he will not be aware of which patients are at risk and therefore what management steps must be taken. The simple step of sending a blood sample for blood grouping and antibody screening at the first prenatal visit in every pregnancy must never be neglected. Knowledge that the patient is Rh-positive is not sufficient; the occasional Rh-positive woman may develop atypical blood group antibodies which may be just as lethal as Rh antibodies, (anti-e and Kell are the commonest) and require the same type of management.

#### TRANSPLENTAL HEMORRHAGE

The obstetrician should also be aware of the risks of Rh-immunization in certain situations. The mode of exposure of the Rh-negative woman to Rh-positive red cells is by fetal transplacental hemorrhage.<sup>4</sup> With the development of the acid elution technique for differentiating fetal from adult red cells by Kleihauer et al<sup>5</sup> in 1957 a very sensitive method became available for determining the incidence and size of fetal-maternal hemorrhage and relating transplacental hemorrhage to risk of immunization.

About 50% of women show evidence of transplacental

hemorrhage at some time during pregnancy or immediately after delivery.<sup>6</sup> In half of these the amount of the hemorrhage is less than 0.1 ml of fetal blood. Less than 1% of women will have more than 5 ml and only 0.2% will have more than 30 ml of fetal blood in their circulation. Cesarean section and manual removal of the placenta increase the frequency of transplacental hemorrhage.

Incidence and amount of transplacental hemorrhage are less in early pregnancy, increasing as gestation progresses. Very small hemorrhages may be found by the eighth week in 5 to 15% of pregnancies. During the third trimester, hemorrhages may be found in up to 20% of pregnancies and occasionally volumes may be considerable. Toxemia is associated with more and larger hemorrhage. External version and abruptio placentae have also been implicated.

Amniocentesis carries a risk. Prior to placental localization, 11.2% of 410 amniocenteses in Winnipeg were associated with transplacental hemorrhage,<sup>7</sup> many in excess of 1 ml of fetal blood. Ultrasound placental localization reduces the risk of transplacental hemorrhage but does not remove it entirely.

Abortion is associated with a significant incidence of transplacental hemorrhage. Volumes following spontaneous abortion are usually less than 0.1 ml. Transplacental hemorrhage following therapeutic abortion occurs in up to 20% of cases and in 4% the volume will be greater than 0.2 ml.

#### THE INCIDENCE OF RH-ISOIMMUNIZATION

As might be expected, the volume of transplacental hemorrhage influences the risk of Rh-isoimmunization of the pregnant woman. If the observed volume of transplacental hemorrhage is always less than 0.1 ml of fetal blood, the incidence of overt Rh-immunization appearing within 6 months of delivery is about 3%.<sup>8</sup> If volumes greater than 0.1 ml are found, the observed incidence in the same period is 14%.<sup>8</sup>

The risk of demonstrable Rh-immunization within 6 months after delivery of the first Rh-positive ABO compatible infant is about 8%.<sup>9</sup> Development of a secondary immune response in the next Rh-positive pregnancy due to "sensibilization" as a result of the first is also 8%.<sup>9</sup> Therefore, the overall risk of Rh-immunization as a result of the first Rh-positive ABO compatible pregnancy is about 16%. If sensitive manual enzyme and/or Auto A<sub>1</sub> zeta antibody screening methods are used more instances of overt Rh-immunization will be detected and less "sensitized" women will be identified due to a secondary immune response in the next pregnancy. However, the overall 16% incidence of Rh-immunization will remain the same.<sup>9</sup>

The risk of Rh-immunization with subsequent Rh-

## RH-ISOIMMUNIZATION

positive ABO compatible pregnancies has been stated to be the same but this is not altogether true. As parity increases, the number of good "responders" will diminish through prior sensitization and the number refractory to Rh antigen will be increased relatively. By the end of the fifth Rh-positive ABO compatible pregnancy there is at least a 50% chance that Rh-immunization will have developed.

ABO incompatibility of the Rh-positive fetus with his Rh-negative mother confers some protection against Rh-immunization. The protection may be due to the destruction of the ABO incompatible fetal red cells in the maternal circulation and removal of red cell debris by phagocytes in the liver, an organ with a relatively small number of potential immunocytes. The protection conferred by ABO incompatibility is only partial, the risk of Rh-immunization following an ABO incompatible Rh-positive pregnancy being about 1.5 to 2%.<sup>10</sup>

A significant number of Rh-negative women are Rh-immunized during pregnancy or within 3 days after delivery (1.5 to 2.0%).<sup>11</sup> This important problem will be considered in detail in the discussion of problems of Rh prophylaxis.

Since transplacental hemorrhage occurs after abor-

tion, one would expect abortion to carry with it some risk of Rh-isoimmunization. This risk has been reported to be as high as 4.3%,<sup>12</sup> although 2 to 3% is probably a truer estimate of the risk. Therapeutic abortion appears to carry a somewhat higher risk than spontaneous abortion. Although the risk would appear to be very low in the first 6 to 8 weeks, it becomes significant by 12 weeks' gestation.

### PATHOGENESIS OF ERYTHROBLASTOSIS FETALIS

The underlying pathogenesis of erythroblastosis fetalis is hemolysis of fetal Rh-positive red cells by maternal IgG Rh antibody (anti-D). The result is fetal anemia and increased production of erythropoietin. Initially, all marrow resources are called into play. If these are insufficient, extramedullary sites, primarily liver and spleen, are called into play with the release of immature nucleated red cells (erythroblasts) into the circulation (Figure 1). Enlargement of the liver and spleen is one of the diagnostic hallmarks of erythroblastosis fetalis.

### PATHOGENESIS OF HYDROPS FETALIS

Twenty to twenty-five percent of fetuses with Rh erythroblastosis have such severe hemolysis that they

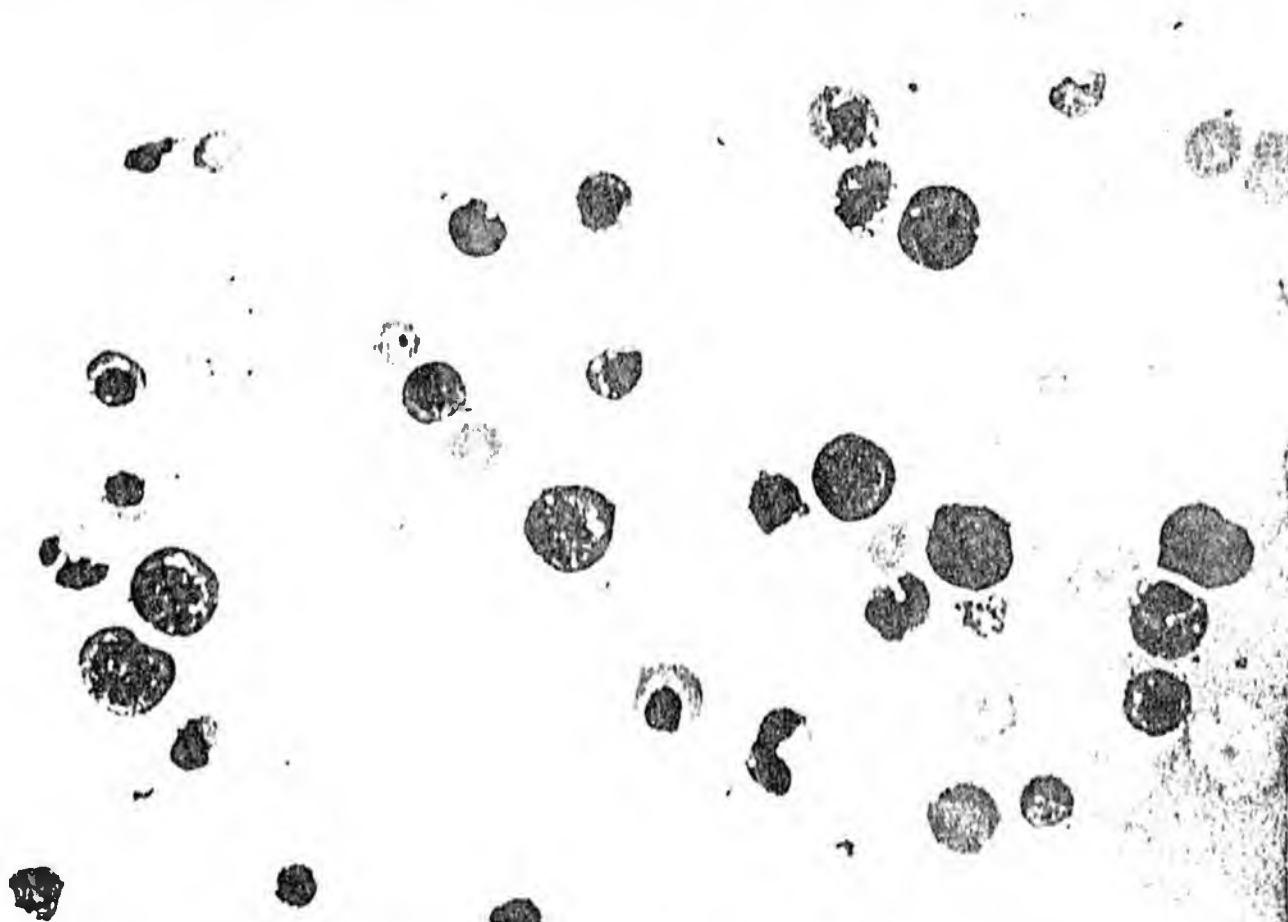


Fig 1. Cord blood smear from infant with severe erythroblastosis. nucleated cells are in the erythroid series from normoblasts to early erythroblasts

ultimately develop universal edema with extreme ascites (hydrops fetalis). It was originally thought that hydrops fetalis was due to fetal heart failure caused by progressive anemia and resultant hypervolemia. Although heart failure will develop in the hydropic neonate if he lives long enough, it is rarely present at birth and is rarely, if ever, the primary cause of hydrops fetalis.

With severe hemolysis and extensive hepatic erythropoiesis, there is a marked distortion and enlargement of hepatic parenchyma by islets of erythropoiesis. Portal and umbilical venous hypertension develop. Placental edema and trophoblastic hypertrophy occur. There is diminution in placental transfer of nutrients to the fetus. Ascites appears as a result of portal hypertension. Distortion of hepatic cell cords and reduction of blood flow due to obstruction reduces the synthesizing capacity of the liver. Hypoalbuminemia develops. As hypoproteinemia increases, ascites becomes more severe and then generalized edema appears. Finally, because of hypoproteinemia and portal hypertension, the edema and ascites become extreme (anasarca). In the final stage of hydrops, hydrothorax with compression hypoplasia of the lungs and pulmonary edema make adequate respiratory exchange impossible after delivery.

Although the above explanation is partially hypothetical,<sup>11</sup> experimental studies have shown that hypervolemia is not usually present at birth<sup>12</sup> and therefore the heart failure theory as the primary cause of hydrops is not tenable. The portal hypertension-liver failure hypothesis explains the variable relation of hydrops to hemoglobin concentrations in the fetus. Because the condition of hydrops is due to hepatic dysfunction and not anemia, some fetuses become hydropic with hemoglobin levels of 7 g/100 ml or higher, others are not hydropic with hemoglobin levels below 3 g/100 ml.

#### IDENTIFICATION OF THE FETUS AT RISK OF BECOMING HYDROPIC

When a physician discovers that his Rh-negative pregnant patient is Rh-immunized, he must be able to predict accurately whether the fetus is severely affected and if so, at what gestation hydrops will develop. It is imperative that only fetuses who will not survive past 34 to 35 weeks' gestation are subjected to fetal transfusion and that only these babies and those who will become hydropic between 34 to 40 weeks' gestation are delivered early. It is also essential to select the latest period for initial fetal transfusion and early delivery compatible with intact survival. The risk of death from fetal transfusion is at least 15% at 22 weeks' gestation and remains at about 10% throughout gestation if the placenta is anterior. The risk is around 3% for second, third, and fourth transfusions after 28 weeks' gestation if the placenta is not anterior.

In order to assess the risks of hydrops developing

when the pregnant patient is Rh-immunized, the obstetrician has three considerations—history, Rh antibody titer, and amniotic fluid spectrophotometric readings, each of which will be considered in some detail.

#### HISTORY OF PREVIOUSLY AFFECTED SIBLINGS

Erythroblastosis may remain of the same degree of severity in subsequent pregnancies or become progressively more severe. A sensitized woman who has had mildly affected fetuses in two or more pregnancies is likely, but by no means certain, to have a mildly affected baby in a subsequent pregnancy. The other pattern is one of increasing severity from mild to hydropic with or without an intervening moderately affected infant. Following one hydropic fetal death, the risk of hydropic fetal death of a subsequent Rh-positive fetus is at least 90%. Infrequently, but not rarely, subsequent disease may be less severe and a moderately severely affected easily treated infant may be born near term after an earlier hydropic fetal death.

Unfortunately, history is not helpful in a first sensitized pregnancy where the risk of hydrops, contrary to general belief, is about 8%,<sup>13</sup> nor is it helpful when there is a past history of severe disease and the husband is heterozygous for the Rh factor (D). A history of previous hydropic stillbirth does not indicate at what stage of gestation a subsequently affected fetus will become hydropic. Treatment of impending hydrops at 23 to 24 weeks' gestation is vastly different than treatment of impending hydrops at 36 to 37 weeks' gestation.

#### MATERNAL Rh ANTIBODY TITER

Contrary to beliefs held by many, Rh antibody titers, if carried out by the same individuals using the same techniques and the same Rh-positive test cells, are of some prognostic significance. However, since other factors such as the binding constant of the Rh antibody, the Rh antigen content of the fetal red cell membrane, and the ability of the fetus to replace destroyed red cells without compromising hepatic function are also important, one would not expect the antibody titer to reflect severity of erythroblastosis with great accuracy.

Before discussing the significance of Rh antibody titers in predicting the fetus at risk of becoming hydropic, a brief description of methods and titers is necessary.

#### Saline Titers

Serial dilutions of maternal serum containing Rh antibody are mixed with Rh-positive red cells suspended in isotonic saline. Only IgM antibody will produce agglutination of red cells suspended in saline. The highest dilution at which agglutination occurs is the saline titer (1:1, 1:2, etc). The titer indicates the presence and, very crudely, the amount of IgM antibody. Usually the saline titer is low since most immunized women produce little, if any, IgM Rh antibody.

*Albumin Titers*

Serial dilutions of maternal serum containing Rh antibody are mixed with Rh-positive red cells suspended in a thicker more viscous medium (usually bovine serum albumin). Both IgM and IgG Rh antibody will agglutinate Rh-positive red cells suspended in albumin. The highest dilution at which agglutination occurs is the albumin titer, (1:1, 1:8, 1:64, etc). If the saline titer is low, indicating little or no IgM antibody, the albumin titer is a crude but reasonable measurement of IgG Rh antibody (the antibody that crosses the placenta and causes fetal red cell destruction). If there is a significant saline Rh antibody titer present, the albumin titer represents a mixture of IgM and IgG Rh antibody and therefore is less helpful. IgM Rh antibody can be destroyed by mercapto-ethanol. Subsequent reiteration by the albumin technique will then allow a more accurate determination of the IgG Rh antibody level.

*Indirect antiglobulin titers*

Serial dilutions of maternal serum containing the Rh antibody are incubated with Rh-positive red cells (usually for 1 hour). Red cells are then washed with isotonic saline and mixed with antihuman globulin (Coombs test serum, made by injecting human serum into another animal species (rabbits, guinea pigs, goats, etc). The greatest dilution at which the antihuman globulin produces agglutination is the indirect antiglobulin Rh antibody titer (1:1, 1:16, 1:128, etc). Antiglobulin Rh antibody titrations are more sensitive than the albumin method (a titer of 1:64 by the antiglobulin method corresponds approximately to a titer of 1:16 by the albumin method).

It cannot be emphasized too strongly that techniques of antibody titration vary greatly in sensitivity from one laboratory to another. It is imperative therefore that the obstetrician become familiar with the methods and the significance of the titers reported by the laboratory which he uses. The titers which indicate that a fetus is at risk of developing hydrops vary from laboratory to laboratory and the figures quoted in this review pertain only to titers carried out by the Rh Laboratory in Winnipeg, using an albumin titration method.<sup>15</sup>

In a first sensitized pregnancy or in a subsequent pregnancy where preceding affected infants did not require exchange transfusion, an albumin Rh antibody titer of 1:8 or less is not associated with stillbirth before term. A titer of 1:16 prior to 32 weeks' gestation carries a 10% risk, 1:32 a 25% risk, 1:64 a 50% risk of hydrops developing before term if the fetus is Rh-positive.<sup>15</sup> If there has been a preceding history of hydrops or severe Rh erythroblastosis requiring fetal transfusion and/or early delivery, subsequent affected fetuses may become hydropic with titers as low as 1:4 or 1:8.

To determine whether there is an Rh antibody level which places the fetus at risk, it is essential that the isoimmunized women have Rh antibody titer estimations at regular intervals. We suggest every 4 weeks prior to 26 weeks' gestation, every 2 weeks thereafter. Unfortunately, antibody titers are rarely helpful in differentiating an Rh-positive from an Rh-negative fetus when the husband is heterozygous. Rarely does the titer rise during such a pregnancy.

Assessment of maternal history and Rh antibody titer is not sufficiently accurate to be the basis for institution of correct management of the Rh-immunized mother and her fetus. In one series of 426 isoimmunized pregnancies (from 1954 to 1961), in which there were 67 stillbirths and neonatal deaths, and 54 babies salvaged only by early delivery, the degree of severity of erythroblastosis, using history and titer in the 121 most severely affected fetuses, could only be predicted accurately in 62% of cases.<sup>15</sup>

## AMNIOTIC FLUID SPECTROPHOTOMETRY

The introduction of amniotic fluid spectrophotometry by Bevis in 1956<sup>16</sup> and its subsequent refinement by Liley<sup>17</sup> and others has completely revolutionized the prediction of severity of Rh erythroblastosis fetalis. Most methods in use depend on the spectrophotometric measurement of bilirubin in amniotic fluid, the amount of bilirubin present being related to severity of erythroblastosis.

It is beyond the scope of this report to describe all the various methods used and to weigh the pros and cons of each. However, a careful comparison by Bartson<sup>18</sup> of the various methods in use in 1970<sup>18</sup> revealed no particular advantage of one over another. Of far greater importance than the actual method of measurement is the familiarity and experience of the obstetrician with the significance of the readings reported to him by the laboratory to which he sends amniotic fluids for testing.

## THE LILEY METHOD (AS USED BY THE Rh LABORATORY)

Liley's method reports optical density rises at 450 m $\mu$  ( $\Delta OD_{450}$ ) in specific figures, allowing accurate comparison of measurements from one laboratory to another. Amniotic fluid, once obtained, is protected from light which oxidizes bilirubin to colorless compounds *in vitro* as it does *in vivo*. It is then centrifuged and filtered. Optical density readings are made over the wavelength range 700 to 350 m $\mu$ , using a good quality spectrophotometer. The readings are plotted either automatically or manually on semilogarithmic graph paper (Figure 2), using wavelength as the horizontal linear coordinate and optical density as the vertical logarithmic coordinate. The readings are joined. A characteristic rise in optical density at 450 m $\mu$  is found. This rise is proportional to the degree of severity of Rh disease in the fetus.

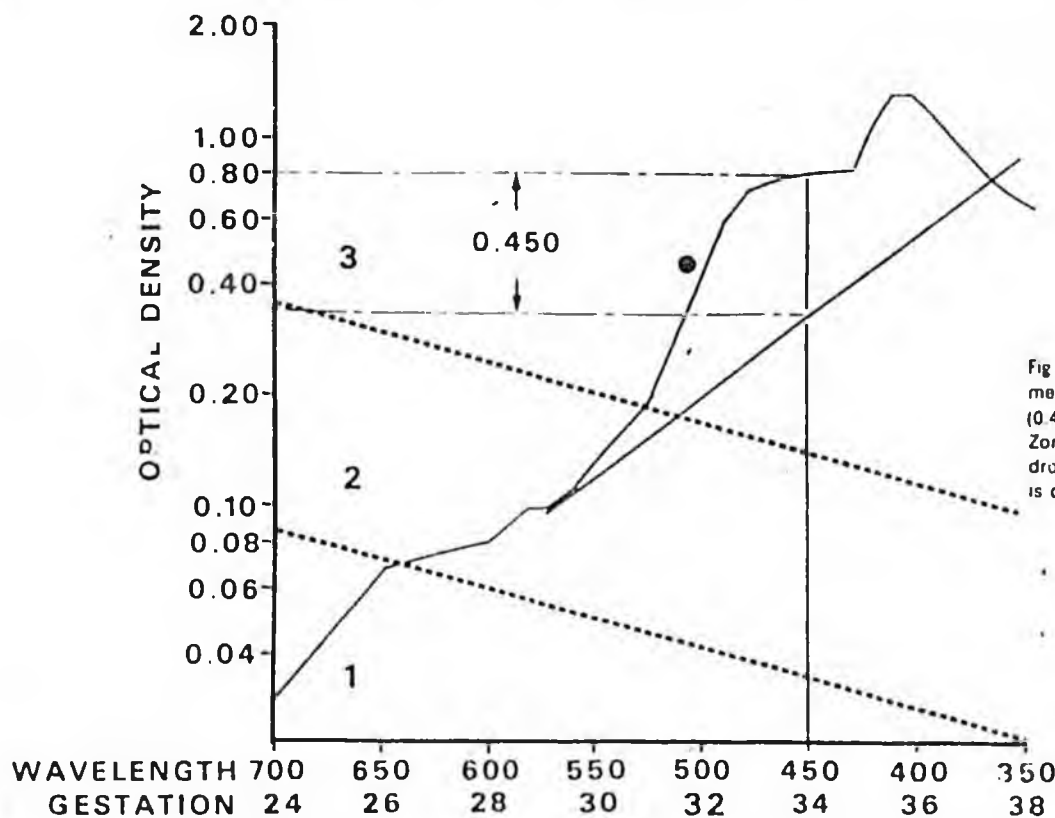


Fig 2. Amniotic fluid spectrophotometric reading, Liley method.  $\Delta OD_{450}$  (0.450 in this example) falls into Zone 3, indicating impending hydropic death; further rise at 405  $m\mu$  is due to heme pigment

A further rise at 405  $m\mu$  unaccompanied by 540 and 580 peaks is due to heme pigment. Since other factors contribute to optical absorption across the entire spectrum, the rise in optical density, i.e., the deviation from linearity, at 450  $m\mu$  is the figure of prognostic importance. This figure is obtained by drawing a tangent joining the curve at 550  $m\mu$  to that at 365  $m\mu$  and measuring from the point at which this line intersects 450  $m\mu$  to the actual optical density reading at 450  $m\mu$  (Figure 2).

The 450  $m\mu$  optical density rise, once obtained, must then be replotted using gestation as the arithmetic horizontal coordinant. Such replotting is necessary because the normal fetus produces bilirubin in early gestation which reaches peak levels at 23 to 25 weeks' gestation. The spectrophotometric graph is divided into three zones (Figures 2 and 3). Fluids falling into the upper zone (Zone 3) indicate severe disease, usually impending fetal death; fluids falling into the lower zone (Zone 1) an Rh-negative infant or an Rh-positive baby with minimal anemia but the possibility of requiring exchange transfusion. Fluids in the middle zone (Zone 2) indicate intermediate disease, becoming more severe as the optical density rise approaches the Zone 3 boundary.

The slope of the boundaries demarcating the three zones indicates that, as gestation progresses and the amniotic fluid bilirubin normally present diminishes, the same optical density rise is indicative of more severe erythroblastosis. Although single amniotic fluid examinations after 29 weeks are reasonably accurate in pre-

dicting severity of disease, serial fluid examinations, plotting consecutive 450  $m\mu$  optical density rises and determining the slope of the serial rises in relation to the zone boundaries, give a more accurate index of severity of erythroblastosis (Figure 3).

The following statements are made on the basis of 2823 amniotic fluid examinations carried out on 997 isoimmunized women from December 15, 1961, to February 28, 1978 (Table 1).<sup>19</sup>

1) A single amniotic fluid optical density rise of 0.400 or higher at any stage of gestation indicates hydrops fetalis at the time of the amniocentesis in 65% of cases.

2) Hydrops fetalis may be present with amniotic fluid 450  $m\mu$  optical density rises as low as 0.250 at 28 weeks' gestation (0.180 on one occasion).

3) If serial amniotic fluid 450  $m\mu$  optical density rises show an ascending slope and the final fluid reaches into the upper 75 to 80% of Zone 2 by 28 weeks' gestation, delay of fetal transfusion until a further examination shows a rise into Zone 3 frequently results in hydrops fetalis.

4) If an optical density rise is in mid Zone 2, a delay in repeating the amniocentesis for 2 weeks may result in a Zone 3 fluid and hydrops at the time of the second examination.

5) On rare occasions a single reading of 0.200 to 0.250 at 22 to 24 weeks' gestation may be associated with an Rh-negative fetus.

Serial amniotic fluid spectrophotometry has increased

## RH-ISOIMMUNIZATION

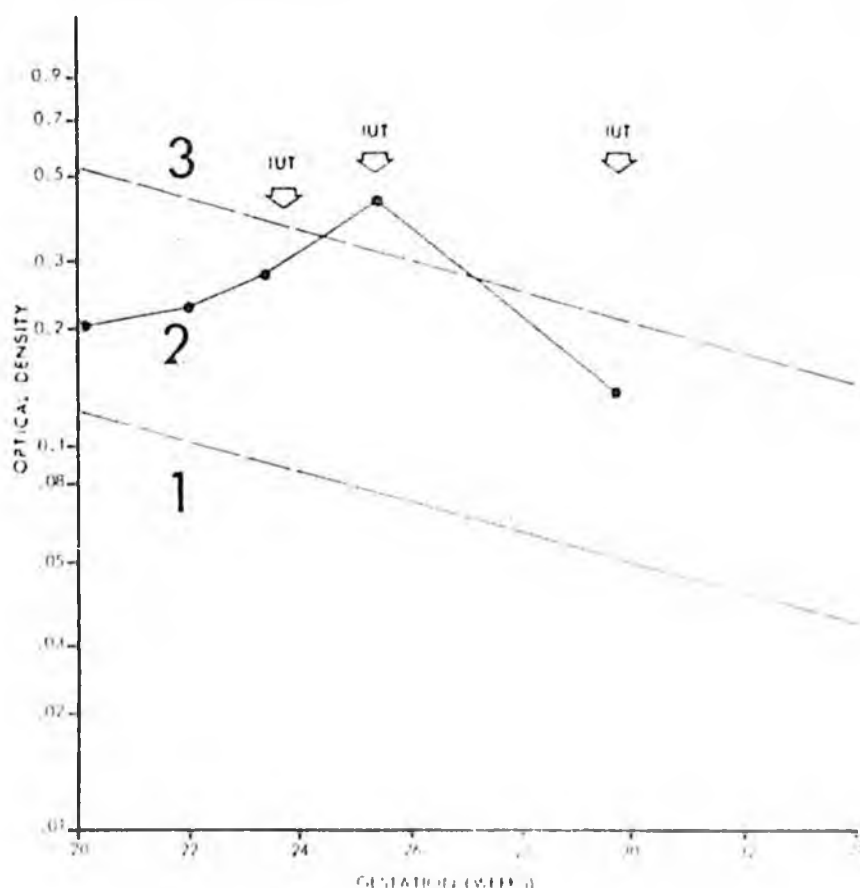


Fig 3. Serial  $\Delta OD_{490}$  readings; first IUT when  $\Delta OD_{490}$  at 75% level Zone 2;  $\Delta OD_{490}$  in Zone 3 at second IUT; fetus not hydropic;  $\Delta OD_{490}$  at 65% level in Zone 2 at third IUT; fetus survived.

the accuracy of prediction of severity of erythroblastosis to 90 to 95% (Table 1).<sup>26</sup> However, life-threatening spectrophotometric inaccuracies resulting in too early or too late intervention occur in 2 to 3% of isoimmunized pregnancies.

### OTHER METHODS OF ASSESSMENT

The reader is referred to the papers of Freda, Robertson, Knox et al, Watfield, Queenan<sup>21-25</sup> and others for description of the spectrophotometric methods of assessing severity of erythroblastosis which they use.

Methods other than simple spectrophotometry such as the chloroform extraction method of Brazie et al,<sup>26</sup> the bilirubin protein ratio of Cherry et al,<sup>27</sup> and biochemical methods of measuring bilirubin in amniotic fluid<sup>28</sup> have been extolled by their proponents. There is no convincing evidence that there is any great improvement in predictive accuracy with their use.

Similarly, urinary and amniotic fluid estriol levels have been examined<sup>29</sup> and have not been found of value in predicting impending hydrops early enough for preventive management measures to be undertaken.

### TECHNIQUE OF AMNIOCENTESIS

Because the hazards of transplacental hemorrhage with an increase in maternal antibody titer and in-

creased severity of erythroblastosis are present if the placenta is penetrated at amniocentesis, initial amniocentesis should be preceded by placental localization, preferably by an ultrasound method or by a radioisotope technique if ultrasound is not available. If the placenta is situated on the anterior wall of the uterus, amniocentesis should be carried out in the ultrasound department under direct ultrasound guidance. With its use, the placenta can usually be avoided and a blood free amniotic fluid sample obtained. Direct ultrasound guid-

TABLE 1. RESULTS OF AMNIOIC FLUID SPECTROPHOTOMETRY (LILLY METHOD)

Zone of last fluid examination	Number of women	Prediction inaccurate (%)	Prediction inaccurate; that was life threatening* (%)
1	231	2.6	1.3
2	174	9.3	4.0
3	292	4.7	2.7
TOTAL	697	5.5	2.4

\* On the basis of the inaccurate amniotic fluid the treatment embarked on (early delivery or fetal transfusion) or withheld placed the life of the fetus in jeopardy.

ance also allows insertion of the needle to the proper depth to obtain amniotic fluid with the least trauma possible.

The procedure is carried out under aseptic technique. A preamniocentesis clotted blood sample should be taken—about 10 ml of amniotic fluid is aspirated and a postamniocentesis clotted blood sample is obtained. The amniotic fluid is sent for spectrophotometry and after 32 weeks' gestation for L/S ratio as well. The two blood samples are sent for Kleihauer fetal cell screening and Rh antibody titers.

#### MATERNAL AND FETAL HAZARDS WITH AMNIOCENTESIS

Maternal hazards following amniocentesis are negligible. Infection can be avoided with careful attention to aseptic technique. Precipitation of labor has been reported as a rare complication as has abruptio placentae also.

The main hazards of the procedure are fetal. On rare occasions, direct trauma to the fetus has occurred<sup>10</sup> but the most important hazards which have already been alluded to are placental trauma, transplacental hemorrhage, and increased severity of erythroblastosis. Although exsanguination from massive transplacental hemorrhage is a real risk with placental trauma at fetal transfusion, it should rarely, if ever, occur at amniocentesis.

#### SOURCES OF ERROR IN AMNIOTIC FLUID SPECTROPHOTOMETRY

Blood, either maternal or fetal, if present in amniotic fluid, produces optical density peaks at 580, 540, and 415  $m\mu$  which destroy the validity of the 450  $m\mu$  bilirubin reading. Methemalbumin which produces a characteristic 405  $m\mu$  peak decreases the 450  $m\mu$  optical density rise. Meconium very markedly increases the 450  $m\mu$  optical density peak. Exposure to light destroys bilirubin by photooxidation. Unless the sample is protected from light it will give a false low reading.

Occasionally, aspiration of fluid at amniocentesis other than amniotic fluid will be a source of error. Maternal urine produces no 450  $m\mu$  peak. In the presence of a hydroptic fetus, ascitic fluid may inadvertently be obtained. Ascitic fluid is a clear yellow and is more viscous because of its high protein level. Bilirubin levels are higher in ascitic fluid which usually has to be diluted two or three times for optical density readings to be possible. The fluid has its highest absorption peak at 460  $m\mu$ . The 450  $m\mu$  optical density rise is usually greater than 1.500.

Congenital anomalies such as anencephaly and obstructive anomalies of the upper gastrointestinal tract such as tracheoesophageal fistula and duodenal or jejunal atresia will produce marked 450  $m\mu$  optical density

rises which may be misleading if the mother coincidentally is Rh-immunized.

#### INDICATIONS FOR AND TIMING OF AMNIOCENTESIS

If an isoimmunized woman has had a previous still-born infant or an infant requiring exchange transfusion, amniocentesis is indicated no matter what the titer. Initial amniocentesis in this case should be undertaken at 20½ to 21 weeks' gestation. In the absence of such a history, a decision to carry out amniocentesis is made on the basis of an antibody titer alone. Using Winnipeg Rh Laboratory titers, if the albumin titer never exceeds 1:8, amniocentesis is not carried out. If the albumin titer is steady at 1:16 or higher, initial amniocentesis is undertaken at 20½ to 21 weeks' gestation. If the titer is initially below 1:16 but reaches or exceeds 1:16 at any time between 20 and 36 weeks' gestation, immediate amniocentesis is carried out. Repeated amniocenteses are carried out at 5- to 21-day intervals depending on the optical density of the preceding test. In many instances, weekly amniocenteses may be necessary for 5 to 6 weeks or even longer before the frequency of the procedure may be reduced or definitive treatment undertaken.

#### MANAGEMENT OF THE ISOIMMUNIZED PREGNANCY WHERE HYDROPS IS NOT A FACTOR

If history and antibody titer have precluded the need for amniocentesis or if serial spectrophotometric readings have remained consistently parallel to the zone boundaries in the lower half of Zone 2 or have dropped into Zone 1 or the lower half of Zone 2, the mother may be allowed to deliver at or near term. We would suggest induction, if feasible, at 38 to 39 weeks' gestation. In the presence of a history of severe erythroblastosis and/or an albumin titer of 1:16 or higher and a heterozygous husband, spectrophotometric readings remaining in or falling into Zone 1 or low Zone 2 indicate that the fetus is almost certainly Rh-negative and the mother should be allowed to go into spontaneous labor. If the husband appears to be homozygous for Rh and the last optical density reading falls into the 30 to 60% area of Zone 2, induction should be carried out at 37 to 38 weeks' gestation if the mother is obstetrically suitable and her dates are accurate. On no account should she be allowed to go past term. If there is any uncertainty regarding the gestation of the fetus, pulmonary maturity should be determined by an amniotic fluid L/S ratio prior to delivery.

#### MANAGEMENT WHEN THE FETUS IS AT RISK OF DEVELOPING HYDROPS FETALIS

##### Early Delivery

When the 450  $m\mu$  optical density rise reaches the upper 75 to 80% level in Zone 2 or an initial reading falls into Zone 3 after 34 weeks' gestation, prompt induction

and delivery should be carried out if an amniotic fluid L/S ratio indicates pulmonary maturity. If the L/S ratio is less than 2.0:1 and the placenta is not anterior, we have, in recent years, elected to carry out an initial fetal transfusion at 34 weeks' gestation, a second at 35½ weeks, and delivery at 37 to 37½ weeks. In the presence of an anterior placenta we will elect early delivery at 34 weeks' gestation even if the L/S ratio is below 2.0:1, preferring to accept the hazards of respiratory distress rather than the increased risk of fetal death at intrauterine transfusion when there is an anterior placenta.

#### *Intrauterine Fetal Transfusion*

Prior to the introduction of fetal transfusion, induced delivery as early as 32 to 33 weeks' gestation was acceptable because no other treatment was available. Since about 8% of all affected fetuses will become hydropic before 32 to 33 weeks' gestation, 8% had to be accepted as the irreducible perinatal mortality from Rh-immunization before 1963.<sup>18</sup> The introduction of fetal transfusion by Eiley in that year<sup>19</sup> completely transformed the outlook for these most severely affected of all erythroblastotic fetuses.

#### *Physiology of Intrauterine Fetal Transfusion*

Red cells infused into the peritoneal cavity are absorbed intact via the subdiaphragmatic lymphatics into the right lymphatic duct and thence into the circulation. If whole blood is injected, plasma is absorbed more rapidly than red cells and there may be a further drop in hemoglobin levels of 1.0 to 1.5 g/100 ml in the first 48 hours, a drop likely to be detrimental to the already anemic erythroblastotic fetus. Tightly packed red cells, negative for the antigen to which the mother is isoimmunized (Rh-negative if she has a Rh antibody), with the least amount of residual plasma are used for fetal transfusion. Since there is no way of determining the ABO status of the fetus, Group O blood is recommended no matter what the ABO constitution of the father and mother. The blood should be drawn not more than 24 hours prior to the transfusion and should be cross-matched against the mother's serum.

In the absence of ascites about 12% of the red cells infused into the peritoneal cavity are absorbed daily. Absorption is therefore complete in 8 to 9 days. The volume infused is limited by the capacity of the fetal peritoneal cavity. If excessive volumes are infused, intraperitoneal pressure rises above umbilical venous pressure, placental circulation is obstructed and the fetus dies.<sup>20</sup> In the early fetal transfusion era, infusion of excessive volumes of blood was a not infrequent cause of unexplained fetal death.

Intraperitoneal pressure may be monitored during

fetal transfusion, discontinuing the transfusion when the pressure reaches 10 mmHg. However, the introduction of a pressure transducer with the catheter may increase the risk of significant loss of transfused blood back into the amniotic fluid when the catheter is withdrawn. If the following transfusion volume formula is followed, intraperitoneal pressures will not be excessive and placental umbilical blood flow will not be interfered with: gestation in weeks, minus 20, times 10 ml (at 24 weeks, 40 ml, at 30 weeks, 100 ml).<sup>21</sup>

Ability to estimate residual donor hemoglobin concentration in the fetal circulation at intervals following fetal transfusion is important in determining the intervals between fetal transfusion and the appropriate time after 34 weeks for induction and delivery. At birth the transfused baby will have about 55% of all the theoretically available residual red cell donor hemoglobin in his circulation. The remainder will be in the adnexa or will have been lost in the transfusion process.

If one uses 55% as the constant, fetal weight charts at various gestations, and 85 ml/kg fetal body weight as fetal blood volume, the increase in hemoglobin concentration expected from a fetal transfusion of a known amount of red cell hemoglobin can be calculated. By allowing for an attrition rate of 1/120 of donor red cells per day and calculating the increase of blood volume as fetal weight increases, the donor hemoglobin level at any time in the future may be calculated within an accuracy range of plus or minus 1 g/100 ml.<sup>22</sup>

The aim of fetal transfusion is to maintain a donor hemoglobin level in the fetus of 10 to 11 g/100 ml. The interval between the first and second fetal transfusion is 10 days; subsequent intervals are approximately 4 weeks, the last transfusion being usually no later than 33½ to 34 weeks' gestation with delivery again being approximately 4 weeks after the last transfusion.

#### FETAL TRANSFUSION OF THE HYDROPIC INFANT

The purpose of fetal transfusion is that it be carried out early enough to prevent development of hydrops fetalis. However, in 25 to 30% of cases the fetus will be hydropic (as evidenced by the presence of gross ascites) at either the first or second transfusion. The hydropic fetus does absorb erythrocytes from the peritoneal cavity adequately, almost if not as efficiently as does the nonhydropic fetus.<sup>23</sup> The likelihood of survival following fetal transfusion is reduced to 21% if the fetus has ascites at the first transfusion. Since 21% survival is better than no survival, a fetus with ascites should be given the benefit of fetal transfusions.

A considerable percentage of surviving hydropic fetuses, particularly those with gross ascites only at second fetal transfusion, are no longer hydropic at delivery.

Reversal of hydrops with relief of ascites and anasarca may depend on the ability of the liver to regenerate and produce adequate amounts of albumin. It is possible that as donor hemoglobin levels are raised by transfusion, erythropoietin levels drop; if the fetus continues to survive, extramedullary erythropoiesis will be reduced, portal and umbilical venous pressures will fall, hepatic circulation and hepatocellular function will improve, serum albumin levels will rise, and ascites and anasarca will disappear. Whereas ascites lowers the survival rate to 21% at the first fetal transfusion, the salvage rate when ascites is first noted at the second fetal transfusion is 76% (Table 2).

#### Indications For Fetal Transfusion

Since intrauterine fetal transfusion carries with it very definite risks, the procedure should be reserved exclusively for those fetuses who are at risk of becoming hydropic prior to 34 to 35 weeks' gestation. Selection is made by amniotic fluid spectrophotometry, patients subjected to amniocentesis being selected on the basis of history and antibody titer criteria which have already been discussed.

Initial amniocentesis, when indicated, is carried out at 20½ weeks' gestation. Fetal transfusion is indicated when serial amniotic fluid spectrophotometric readings rise into the upper 75 to 80% of Zone 2 prior to 30 weeks' gestation (Figure 3) and into Zone 3 between 31 and 34 weeks' gestation. If the initial reading falls high into Zone 3 ( $\geq 0.400$  at or before 24 weeks,  $\geq 0.350$  at or after 25 weeks,  $\geq 0.300$  at or after 27 weeks,  $\geq 0.250$  at or after 29 weeks, and  $\geq 0.200$  at or after 31 weeks' gesta-

tion), fetal transfusion is carried out on the basis of the single reading.

#### The Fetal Transfusion Team

A word must be said about the personnel, experience, and facilities required before fetal transfusions are undertaken. As the incidence of Rh-immunization declines, the number of candidates for fetal transfusion will become fewer and the necessary expertise to maintain adequate proficiency in the procedure with satisfactory survival rates will be more difficult to achieve. Whereas, in 1964 there were 20 to 25 fetuses requiring fetal transfusion from each million total population, in 1978 there are only 3 to 4. In 1969 the Rh Laboratory Fetal Transfusion Team carried out 78 fetal transfusions on 37 fetuses; in 1977 it carried out 17 transfusions on 7 fetuses.

Although the technique itself is well within the grasp of any capable obstetrician, total management of the woman and her fetus requires not only a highly competent obstetrician but expert neonatal and laboratory input with all the resources of a sophisticated high-risk antenatal and neonatal facility. Each fetal transfusion facility, as a minimum, should deal with at least 4 to 5 fetuses yearly on whom 12 to 16 fetal transfusions are carried out. To accomplish this, each team must draw from a population base of at least 1 to 2 million and have referred to it all fetal transfusion candidates within that population base. It is only in this manner that expertise will be maintained in the carrying out of fetal transfusions and the overall management of the severely

TABLE 2. DATA ON FETAL TRANSFUSIONS PERFORMED BETWEEN JANUARY 2, 1964, AND JANUARY 3, 1978

	First 2 years		Next 4 years		Final 8 years		Total	
	No.	Percent	No.	Percent	No.	Percent	No.	Percent
All fetal transfusions	86		242		293		611	
All fetuses transfused	40		104		113		257	
Liveborn infants	16		68		87		171	
Surviving neonatal period	12	30	61	59	79	70	152	89
Hydrops transfused	14	35	24	23	34	30	72	28
Hydrops surviving neonatal period	1	7	8	33	17	50	26	36
Nonhydrops transfused	26		80		79		185	
Nonhydrops surviving neonatal period	11	42	53	66	62	78	126	68
Neonatal deaths	4	28	7	10	5	9	19	11
Traumatic deaths	15	38	20	29	16	14	51	20
Traumatic death rate/transfusion		17.5		8.6		5.5		8.4

Neonatal deaths: 5 hydrops, 6 respiratory distress syndrome, 4 previable (delivery precipitated by fetal transfusion), 1 incidental (congenital heart disease), 1 *Pseudomonas pneumonia* (membranes ruptured from 20 weeks' gestation), 1 exchange transfusion complication (necrotizing enterocolitis), and 1 Down syndrome (untreated after delivery).

Postneonatal deaths: 1 died at 8 weeks in septic shock, disseminated intravascular coagulation unrecognized gram negative sepsis, 1 died at 12 weeks of sudden infant death syndrome ("cot" death).

affected erythroblastotic fetus and infant who will never disappear entirely from the perinatal scene.

#### *Technique of Intrauterine Fetal Transfusion*

Many modifications of Liley's original method have been devised in an attempt to improve the ease and safety of fetal transfusion. The fetus has been immobilized by a limb impaling technique;<sup>36</sup> image intensification fluoroscopy has been used;<sup>36</sup> blood has been injected down the needle rather than through a catheter<sup>37</sup> or through a Teflon sheath left *in situ* after the needle inside the sheath, which punctured the peritoneal cavity, has been withdrawn.<sup>36</sup> Although these modifications are undoubtedly helpful to some, the Fetal Transfusion Team in the Rh Laboratory has had excellent results using Liley's original technique.<sup>31-33</sup> One very promising modification in certain difficult situations is the insertion of the needle and catheter under direct ultrasound guidance using real time span ultrasonography.

Once fetal transfusion is decided on, 12 to 16 ml of a radioopaque medium is injected into the amniotic cavity and lateral and anteroposterior x-rays are taken (amniogram). The amniograms show placental site, fetal position, and the presence or absence of fetal edema. Fetal edema is not a contraindication to fetal transfusion.

Two to twelve hours later, under sedation, with careful asepsis and local anesthesia, the fetal transfusion is carried out in the x-ray department. Suitable coned anteroposterior and cross table lateral x-rays of the maternal abdomen are taken after the placing of 4 radioopaque markers on the maternal abdomen in a grid over the likely position of the fetal peritoneal cavity. The x-rays determine the site of the fetal peritoneal cavity in relation to the markers and the depth of the fetal peritoneal cavity from the maternal skin surface.

The best position for the fetus is lateral, less ideally in an abdominal anterior position, for then the insertion of the umbilical vessels into the fetal abdomen is the center of the target area. Fetal transfusions should not be undertaken if the fetal back is in an anterior position but every effort should be made to change it to a back lateral position. If this proves to be impossible, fetal transfusion may be undertaken only if real time span ultrasonography is available to allow an oblique insertion of the needle and catheter into the fetal peritoneal cavity under direct guidance.

The presence of an anterior placenta is always a serious complication tripling the risk of fetal transfusion. Every effort should be made to avoid the placenta or if necessary to traverse it as near its periphery as possible. This may involve carrying out external version.

The usual technique carried out by the obstetrician

member of the Rh Laboratory Team, after adequate aseptic and local anesthetic preparation, is to insert the needle (an 18-cm 16-gauge Tuohy needle) directly and vertically in one movement to the required depth as determined from the lateral x-ray exposure. The stylette is withdrawn from the needle and an epidural catheter (Portex) of a diameter that just fits the lumen of the needle is threaded down the needle. If the catheter can be threaded, the tip of the needle lies within a cavity, hopefully the fetal peritoneal cavity. About 25 to 30 cm of catheter is threaded down the needle and the needle is then withdrawn to lie on the maternal abdominal wall. Two milliliters of radioopaque medium is injected down the catheter and a repeat x-ray is taken. If the catheter lies free in the fetal peritoneal cavity, characteristic semilunes of dye outline the fetal small bowel.

In about 50% of cases the fetal peritoneal cavity is catheterized at the first attempt. However, problems may arise particularly if the fetus is small and active. If the catheter threads down the needle but no dye is apparent in the fetal peritoneal cavity, the catheter is probably in the amniotic cavity. This is confirmed by the dye outlining the catheter in the amniotic cavity and may be doubly confirmed by aspiration of amniotic fluid. If the catheter cannot be threaded past the tip of the needle, the needle is not free in a cavity but is embedded in fetal thigh, buttocks, back etc. or in the maternal uterine wall. In this situation, no attempt should be made to force the catheter down the needle. The needle should be withdrawn and redirected. If reinsertion of the needle is unsuccessful, a repeat anteroposterior x-ray is taken to redetermine fetal position.

If on insertion of the needle to the required position and depth, fluid spurts up the needle, the tip of the needle lies in either fetal bladder (fetal urine is almost colorless), or in the peritoneal cavity of a fetus with ascites (the fluid is clear and bright yellow at first fetal transfusion or heavily blood stained if the procedure is a second fetal transfusion). Dye may be injected down the needle to confirm its position in the fetal bladder, although this is unnecessary since the fluid is so characteristic. The bladder is emptied, and the needle withdrawn and reinserted in the same site to the same depth.

A variation of the needle insertion technique which may be used is as follows: the needle is advanced to a depth where the tip is calculated to lie in the amniotic cavity. The stylette is withdrawn, a sterile 5- or 10-ml syringe is attached, and amniotic fluid is aspirated. The needle is then advanced toward the fetal abdomen, aspirating at every centimeter of further insertion. When resistance is encountered with failure of aspiration of fluid, the needle is probably just entering the fetal skin. It is thrust quickly an additional 1 or 2 cm. If aspiration of fluid is still impossible, the catheter is threaded. This

technique should be carried out quickly. There should be no hesitation or delay in the final advance of the needle. Otherwise, the fetus will move away from the sharp needle point. The fluid aspiration method just described should not be used in the presence of an anterior placenta.

Once the catheter has been shown to be in the fetal peritoneal cavity, the fetal transfusion is carried out. Fresh, Group O, Rh-negative blood which has been crossmatched with maternal serum, centrifuged, and has had all of its supernatant plasma and buffy coat removed is now readied for use. The hematocrit of the unit (95) is such that without dilution its viscosity is so great that it cannot be injected down the catheter. Just prior to connection to the transfusion tubing, 12 to 15 ml of sterile 0.9% saline are injected through one of the entry ports of the unit into the blood. This entry port is then attached to the blood infusion set and the side arm of a sterile three-way stopcock is attached to the other end of the set. The unit of blood and saline is then shaken. The fetal peritoneal transfusion catheter is cut off approximately 10 cm from the maternal abdomen and a 22-gauge blunt needle or cannula is inserted into the cut end of the catheter. The hub of the needle or cannula is attached to the stopcock. A 10-ml syringe is then attached to the remaining arm of the stopcock and the transfusion is begun.

The transfusion is carried out in 10 ml aliquots. The fetal heart is monitored by ultrasound at the beginning and end of each 10-ml infusion. It is monitored continuously throughout the final 10 ml of the amount of blood planned to be administered, according to the gestation,  $\approx 20 \times 10$  ml formula. If the fetus is in good

condition, the transfusion produces a tachycardia of 160 to 180 beats/min (occasionally 200). Fetal tachycardia during the procedure is reassuring. Fetal bradycardia early in the procedure is very ominous and usually portends fetal demise. Sudden bradycardia as one approaches the end of the transfusion is an indication for immediate termination of the transfusion.

Following completion of the infusion, the fetal catheter is slowly withdrawn from the fetal peritoneum with careful fetal heart monitoring. Profound fetal bradycardia, probably vagal in origin, may occur. If bradycardia appears, further catheter removal is delayed until the bradycardia disappears. The mother is usually discharged 36 to 48 hours after the procedure.

When ascitic fluid is encountered, an attempt should be made to aspirate fluid before the catheter is threaded. A volume of ascitic fluid equal to the volume of blood to be transfused is aspirated, if possible and the catheter is then threaded. When fetal ascites is present, the dye injected is shown diffusing through the ascitic fluid and no semilunes can be seen (Figure 4). Depending on the amount of residual ascites apparent on x-ray, a further volume may be aspirated. However, no attempt should be made to empty the peritoneal cavity completely. An empiric rule is not to remove more than a volume double that of the proposed transfusion with a maximum removal of 120 to 150 ml.

When more than the proposed transfusion volume of ascitic fluid is aspirated, the total volume of the blood infused is increased by 20 to 30% (50 ml at 24 weeks, 120 ml at 30 weeks, etc). Although digitization of the fetus logically would appear to be valueless, our empiric experience with 44% hydropic fetal survival (26 of 59)

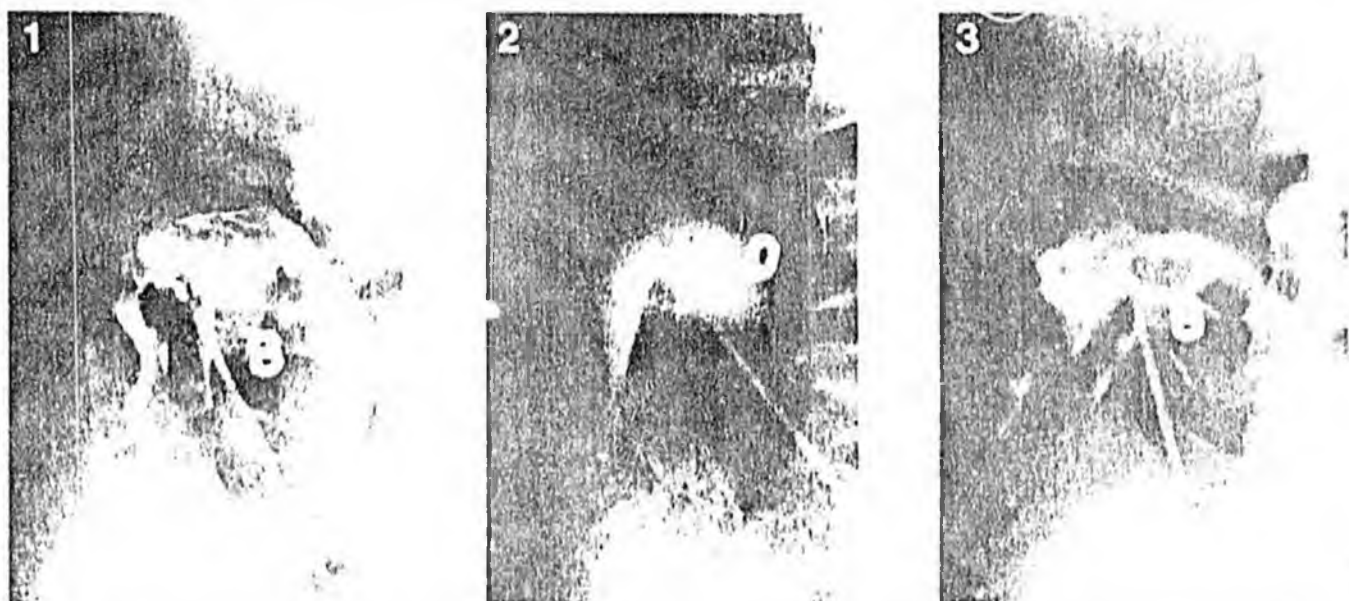


Fig. 4. Radiopaque dye outlining fluid from peritoneal cavity at first IUT (1), gross ascites at second IUT (2), ascites no longer present at third IUT (3)

following its introduction<sup>22</sup> causes us to advise its use (0.035 mg/kg estimated fetal weight of digoxin is infused intraperitoneally). The mother is placed on maintenance digoxin and furosemide orally. The diuretic may be a more important factor than the digoxin in improving the hydropic fetus's chance of survival.

Since the hydropic fetus absorbs blood from his peritoneal cavity adequately,<sup>24</sup> but possibly more slowly, the interval between the first and second transfusions should be lengthened to 12 days. Ascitic fluid, if encountered again, should be aspirated and again digoxin should be instilled. Third and fourth transfusions are carried out at 20- to 22-day intervals if ascites is still present.

#### HAZARDS OF FETAL TRANSFUSION

##### *Maternal Risks*

Fetal transfusions should carry very little if any risk to the mother. Maternal infection can be avoided by very careful attention to aseptic technique. Nevertheless, some fetal transfusion teams, including ours, prescribe oral broad spectrum antibiotic therapy for 12 hours before and 48 hours after the procedure. No complications have been noted following such short term antibiotic use.

Potential serious morbidity may occur if the needle and catheter penetrate maternal tissues and dye is injected into them (maternal muscle, peritoneal cavity, and particularly uterine wall behind the placenta). If the transfusion needle perforates a retroperitoneal maternal sinus, there is a serious risk of introduction of amniotic fluid into the maternal circulation with abruptio and coagulation difficulties.<sup>25</sup>

Administration of hydrochlorothiazide to the pregnant woman with a hydropic fetus has been associated with fatal pancreatitis. When a diuretic is used in such a situation, furosemide should be selected.

##### *Fetal Hazards*

*Early hazards* Fetal risks are considerable. The hazards of oxetransfusion and how they may be prevented have been described. The early major hazard is the puncture of a fetal arterial or major venous vessel or heart by the needle with fetal death either from exsanguination or cardiac tamponade. Since fetal transfusion is basically a blind procedure, the risk of fetal exsanguination cannot be prevented completely. However, avoidance of the placenta as far as possible and taking care not to insert the needle too deeply will reduce the risk.

Provided that a major fetal vessel is not damaged, inadvertent placement of the needle and transfusion catheter in other fetal organs and tissues appears to be

harmless provided that the improper site is recognized, blood is not infused, the catheter is removed, and the needle reinserted properly.

*Precipitation of delivery* by fetal transfusion represents a real hazard to the fetus. Unexpected early delivery occurred in 46 instances in our fetal transfusion series. There were two very fresh stillbirths and 12 neonatal deaths. The neonatal deaths were evenly divided between hydrops fetalis and prematurity. Indeed 4 of the 12 who died were considered to be preivable (less than 28 weeks' gestation).

Of the 32 who survived after unexpected early delivery, 3 were grossly hydropic, being born at 31 <sup>5</sup>/<sub>7</sub>, 31 <sup>6</sup>/<sub>7</sub>, and 31 <sup>6</sup>/<sub>7</sub> weeks' gestation. Of the remaining 29, 2 were born between 29 and 31 weeks' gestation, 10 between 31 and 33 weeks, 16 between 33 and 35 weeks, and 1 at 35 <sup>2</sup>/<sub>7</sub> weeks' gestation.

##### *Late Fetal Hazards*

Donor lymphocyte grafting, with the development of fatal graft versus host disease following fetal transfusion has been reported.<sup>26</sup> It is for this reason that some advise the use of x-radiated blood for fetal transfusions. Animal experiments would lead one to expect that by 21 to 22 weeks' gestation the human fetus should be immunologically mature enough to reject living donor leukocytes. The rare lymphocyte graft and the even rarer graft versus host response probably occurs in the occasional abnormally immunologic immature fetus or one with a specific immunologic defect.

The amount of radiation the fetus receives is significant—up to 3.5 to 4.0 rads in some fetuses in our series.<sup>26</sup> Exposure of the fetus to radiation is unavoidable but should be kept to the absolute minimum compatible with the successful carrying out of fetal transfusion. Expert radiologic assistance with proper coning of the x-ray beam will reduce radiation. The use of fluoroscopy should be kept to a minimum. Our series (some children are now 13 years of age) has none with evidence of radiation injury. However, the period of observation is too short and future generations must be awaited before the true radiation risks of fetal transfusion may be assessed. One instance of acute leukemia in a fetal transfusion survivor has been reported,<sup>27</sup> but this probably does not exceed the expected incidence of acute leukemia in a pediatric population. The use of ultrasound real time span guidance should materially reduce x-r. diation exposure.

*Transient susceptibility* to viral infections in the first year of life with acute recurrent bronchiolitis and bronc. pneumonia of adenoviral or respiratory syncytial viral origin appears to be a very real hazard for some fetal transfusion survivors. The hazard is temporary.

disappearing by 12 to 18 months of age. It may be related more to prematurity than the fetal transfusions themselves.

#### SURVIVAL RATES AFTER FETAL TRANSFUSION

Contrary to recent reports from England,<sup>42,43</sup> there is no question that fetal transfusion represents a major advance in the management of severe Rh-isoimmunization.

The recent report by Hamilton<sup>36</sup> notes excellent survival rates (84.6% in the past 5 years), but apparently he does not transfuse fetuses in whom the diagnosis of hydrops fetalis is made.

Our own results are outlined in Tables 2 and 3. As can be seen survival rates (Table 2) have increased over the years. We can now offer a fetal transfusion candidate an overall 70% chance of having a surviving infant; 50% if the fetus is or becomes hydropic (21% if hydropic at first, 76% if not hydropic at first transfusion); 78% if the fetus is not hydropic at any time.

Although many centers report poor survival rates if fetal transfusions must be started before 26 weeks' gestation, this has not been our experience (Table 3). Although it is true that survival rates are 11% lower if transfusions must be started before 26 weeks' gestation, an overall survival rate of 59% in this most severely affected group of fetuses is nevertheless very encouraging. Indeed, salvage rates are acceptable if there is need to carry out the first procedure as early as 21½ to 23 weeks' gestation (11 of 26 (42%) fetuses in our series).

#### DEVELOPMENT OF FETAL TRANSFUSION SURVIVORS

The majority of fetal transfusion survivors develop normally. In our series 74 of 89 tested at 18 months of age or later are completely normal. Because many survivors are born prematurely and have varying degrees of severity of residual erythroblastosis with the manage-

ment problems (thrombocytopenia, anemia, hyperbilirubinemia, heart failure, and hepatocellular damage) that this entails, there is some evidence of minor neuromuscular problems and mild developmental delay with probably a normal IQ ultimately in 11 of the 89 cases. The remaining 4 are abnormal. One infant who was very premature has a normal IQ, but a moderate spastic hemiparesis, a second who was hydropic and premature has an IQ of 75, and a third, hydropic and very premature, developed hydrocephalus as a result of subarachnoid hemorrhage and has an IQ of 80. One infant who may now be dead, has cerebral agenesis which may or may not be related to the fact that he was hydropic *in utero* but not hydropic at birth.

#### DELIVERY OF THE SEVERELY AFFECTED ERYTHROBLASTOTIC INFANT AND MANAGEMENT AFTER BIRTH

The severely affected erythroblastotic infant who must be delivered early and often has undergone fetal transfusions requires neonatal care and facilities of the highest order. For this reason, delivery should be carried out in a fully developed tertiary perinatal care center where personnel and facilities are available to monitor fetal conditions prior to labor and during labor and delivery, and the skilled neonatal personnel and nursery resources are available to manage a sick premature hemolyzing and occasionally hydropic neonate.

If the placenta is not on the anterior uterine wall and if serial amniotic fluids indicate the need for interference at 34 weeks' gestation, a decision regarding prompt induction of fetal transfusion repeated in 10 days with delivery at 37 weeks' gestation should be made on the basis of an L/S ratio or the presence or absence of stable foam. If the placenta is anterior, delivery should be carried out at 34 to 34½ weeks even if the L/S ratio and/or foam test indicate the risk of respiratory distress. As a

TABLE 3. DATA ON INITIAL FETAL TRANSFUSIONS DONE BEFORE AND AT OR AFTER 26 WEEKS' GESTATION

Time of transfusion	Fetuses														
	Dead														
	Alive			Traumatic deaths				Hydrops <sup>†</sup>				Nonhydrops			
	Total No.	No.	Percent of total	Total No.	Neonatal deaths	Stillbirths	No.	Percent of total	Total No.	Percent of total	Alive	%	Total	No.	%
< 26 weeks' gestation	105	62	59	43	6*	37	27	25	24	23	8	33	81	84	67
≥ 26 weeks' gestation	113	79	70	34	9	25	12	14	35	30	18	51	78	61	78

\* One infant with Down syndrome died of kernicterus because post-liver treatment was withheld.

† Hydrops at first transfusion, survival 21% (7 of 34), hydrops at second transfusion, survival 76% (19 of 25).

general rule one should not allow a fetus who has been transfused to remain undelivered after 37 to 37½ weeks' gestation no matter what the L/S ratio and foam tests show, provided that the duration of gestation is known to be accurate.

Once induction is decided on, every effort consistent with maternal and fetal welfare should be made to deliver the infant via the vaginal route. We achieve this aim in 80% of cases. Resorting to cesarean section should be considered if good labor has not ensued within 16 to 20 hours of rupture of the membranes.

Fetal monitoring by external tocodynamometry and subsequently by scalp clip electronically with concomitant monitoring of uterine contractions is an essential component of management. Scalp vein fetal blood pH measurements, if available, should be carried out if fetal heart monitoring indicates fetal distress. If there is evidence of fetal distress and immediate vaginal delivery is not possible, immediate cesarean section under epidural or some other form of regional anesthesia should be undertaken.

During the course of the mother's labor and delivery, all measures possible to insure adequate oxygenation and optimum condition of the fetus should be carried out. At delivery the cord should be clamped promptly, 10 to 15 ml of heparinized cord blood should be obtained, immediate gentle but thorough resuscitative measures should be undertaken, and the baby given into the care of an expert neonatologist.

The management of the sick premature erythroblastotic newborn is outside of the purview of this review. Suffice it to say that successful management of the primary disease and the complications that may develop in such a sick infant will tax the skills and resources of the most highly developed neonatal intensive care unit and its personnel, and should only be undertaken where such resources are available.

#### OTHER FETAL TRANSFUSION METHODS

Fetal exchange transfusion carried out by open hysterotomy, exteriorization of a leg, and catheterization of the femoral vein has been carried out in the past.<sup>4</sup> The procedure, a major surgical one, has been associated with only 2 surviving infants and was carried out in them at 28 to 32 weeks' gestation, at a time when intra-peritoneal fetal transfusion, technically, would have been relatively easy. Most attempts at fetal exchange transfusion have been followed by prompt labor, the need for further hysterotomy, and neonatal death.

Similarly, incision of the uterus with dissection through the membranes at the placental margin with isolation and catheterization of a major fetal vessel on the placental surface carries with it the same haz-

ards.<sup>4b</sup> When fetal transfusions are indicated, neither of these very dangerous techniques should be resorted to; the method used should be that of Liley or a modification thereof.

#### CONCLUSIONS

The importance of amniotic fluid spectrophotometry, early delivery, and intrauterine fetal transfusion in the management of Rh-isoimmunization have been outlined in some detail. In Manitoba, in the 3-year period ending October 31, 1977, there were only two perinatal deaths from erythroblastosis fetalis, a perinatal mortality rate of 1.5%. Both were losses early in gestation at fetal transfusion: one from trauma, the other from hydrops fetalis. This rate of 1.5% compares favorably with the 14.3% perinatal mortality rate (82 fetuses and infants) for the 3-year period ending October 31, 1964.

However, the rate of 1.5% was only possible with a closely integrated centralized management program utilizing a highly skilled transfusion team and a tertiary neonatal care center of good quality. The generally accepted perinatal mortality rates from erythroblastosis fetalis in other parts of Canada at the present time are on the order of 5 to 10%.

Although an experienced Rh-isoimmunization management team will reduce stillbirths and neonatal deaths from erythroblastosis to a very low level, it will not reduce the perinatal mortality rate to zero. Hydrops fetalis on occasion occurs as early as 22 weeks' gestation; traumatic deaths will occur at fetal transfusion; amniotic fluid spectrophotometry will be life threateningly inaccurate in 2 to 3% of cases. The only means of reducing perinatal deaths from Rh-isoimmunization to zero is to prevent Rh-isoimmunization altogether through a well coordinated comprehensive Rh prophylaxis program.

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delivery. It is best treated by a combination of oral hygiene and a well-balanced diet. An *opisthion*, a focal, highly vascular swelling of the gingiva, is an occasional complication (see Fig. 9-15, p. 247).

**Porphyria.** Acute idiopathic porphyria is a rare metabolic dysfunction caused by an inborn error of porphyrin metabolism. It may present a wide range of symptoms often suggestive of diseases involving the gastrointestinal tract, pelvic organs, and nervous system. Brodie and co-workers (1977) have reviewed the pregnancy experiences of 39 women with this autosomally dominant disease. One woman died; total wastage was 13 percent. The diagnosis must be kept in mind whenever a pregnant woman describes bizarre acute abdominal pain.

#### OTHER VIRAL INFECTIONS

Various viruses have been recovered from the fetus, but only rubella virus, cytomegalovirus, herpesvirus hominis, and varicella-zoster virus are at all likely to be teratogenic. Others that may reach the fetus include the viruses causing measles (rubeola), smallpox (variola), vaccinia, poliomyelitis, hepatitis, Western equine encephalitis, mumps, and the Coxsackie B group.

About 5 percent of pregnancies are complicated by clinically apparent viral infections, according to the Collaborative Perinatal Research Study. When the common cold is excluded, the most frequent viral infections are influenza, flulike disease, herpesvirus infections, viral gastroenteritis, and viral infection of larynx, pharynx, and tonsils.

**Rubella (German Measles).** Rubella, a disease of minor importance in the absence of pregnancy, has been directly responsible for inestimable perinatal loss and serious malformations in the liveborn infant. The relation between maternal rubella and grave congenital malformations was first recognized by Gregg (1942), an Australian ophthalmologist.

**DIAGNOSIS.** The diagnosis of rubella is at times quite difficult. Not only are the clinical features of other illnesses quite similar, but subclinical cases with viremia and the capability of infecting the embryo and fetus do occur. Diagnosis of rubella, therefore, can be made with certainty only by isolation of the virus or by the more practical demonstration of a rising rubella antibody titer in the serum. Absence of rubella antibody indicates lack of immunity. The presence of antibody denotes an immune response to rubella viremia that may have been acquired anywhere from a very few weeks to many years earlier. If maternal rubella antibody is demonstrated at the time of exposure to rubella or sometime before, the mother can be assured that it is exceedingly unlikely that her fetus will be affected.

The nonimmune person who acquires rubella viremia demonstrates peak antibody titers 1 to 2 weeks after the onset of the rash, or 2 to 3 weeks after the onset of viremia, since the viremia precedes clinically evident disease by about 1 week (Cooper and Krugman, 1967). The promptness of the antibody response, therefore, may complicate serodiagnosis unless serum is collected initially within a very few days after the onset of the rash. If, for example, the first specimen was obtained 10 days after the rash, detection of antibodies would fail to differentiate between two possibilities: one, that the very recent disease was actually rubella and, two, that it was not rubella, but the person was already immune to rubella. The demonstration of specific IgM globulin in the pregnant woman indicates a primary infection within the previous month or so. Therefore, specific IgM estimations, if available, are useful for diagnosing recent rubella infection (Field and Murphy, 1972).

**IMMUNIZATION.** There is no known chemotherapeutic or antibiotic agent that will prevent viremia in nonimmune subjects exposed to rubella. The use of gamma globulin for this purpose is not recommended. Brody and co-workers (1965), during a rubella outbreak in an isolated community, gave rela-

tively large doses of gamma globulin to boys but not to girls at the time of, or even before, exposure. The attack rate, measured by seroconversion, among the boys was 44 percent and among the girls 85 percent. The group that received gamma globulin therefore, was only partially protected. The data of Brody and associates also suggest that large doses of gamma globulin given at or before exposure to rubella may only minimize the clinical features of the disease. Viremia without clinically apparent disease can, of course, lead to fetal infection with disastrous consequences.

Even though women who are pregnant or who may conceive within the next 6 weeks or so should not be vaccinated, some states attempted to require women seeking marriage licenses either to have demonstrable immunity or to be immunized. In Colorado during 1971 and 1972, of those without immunity and about to enter wedlock, 21 percent were already pregnant! (Judson et al., 1974). Although the risk appears low (Hayden et al., 1980), rubella vaccine is contraindicated just before and during pregnancy.

The following program for immunizing women of childbearing age susceptible to rubella has proved satisfactory: (1) Identify susceptible women by means of the hemagglutination-inhibition antibody test. The majority of women will be immune to the rubella virus and can be so assured. (2) Nonimmune women are eligible for vaccination only if pregnancy can be avoided for at least 2 months after vaccination. Women least likely to become pregnant are those who have been delivered within the week before vaccination and those who take oral contraceptives in the approved way. Although there is laboratory evidence of prolonged fetal infection and tissue reaction, according to Brandling-Bennett (1974) and Modlin and associates (1976), no infant born alive to a woman vaccinated shortly before or after conception has provided clinical or laboratory evidence of rubella infection. Vaccinelike rubella virus has been recovered, however, from a fetus with histologic evidence of a cataract. The seronegative mother had been immunized 7 weeks before conception. These observations sug-

gest that attenuated rubella virus might be teratogenic when given to a woman early in pregnancy or up to at least 2 months before conception.

Mass vaccination programs in children have been undertaken. A very important question concerning the value of such immunization programs has yet to be answered: Will the antibody titers persist at levels sufficient to maintain immunity or will they fail to leave the woman vaccinated as a child susceptible to rubella?

**EFFECTS OF NATURAL VIRUS.** The numerous reports concerned with the frequency of major fetal developmental defects that are thought to be caused by rubella are difficult to interpret because of the lack of precision inherent previously in the diagnosis of rubella. Forbes (1969) believed that the diagnosis of rubella may have been erroneous in as many as 50 percent of the cases. The frequency of congenital malformations, therefore, is probably higher than some reports have indicated. Rubella during the first month of pregnancy probably causes serious defects in up to 50 percent of the embryos and perhaps even more if those that abort spontaneously are considered. During the second month, the rate appears to be halved to about 25 percent, and during the third month, approximately halved again to about 15 percent.

It is now evident that many infants who are born alive suffer stigmata of continuing intrauterine and neonatal rubella infection. The syndrome of congenital rubella includes one or more of the following abnormalities:

1. Eye lesions, including cataracts, glaucoma, microphthalmia, and various other abnormalities.
2. Heart disease, including patent ductus arteriosus, septal defects, and pulmonary artery stenosis.
3. Auditory defects.
4. Central nervous system defects, including meningoencephalitis.

5. Retardation.
6. Hemolytic anemia.
7. Hepatitis.
8. Chorea.
9. Osteopenia.
10. Chronic hepatitis.

Infants born with the virus are a threat to the adult population because of the possibility of being infected in

Although the incidence of rubella is slight if it occurs after the infant is born, the disease after infection may be heralded by long-term complications. To assess the frequency of rubella infections by rubella virus, the 22 live births considered for period (1975) are being reported beginning with congenital rubella infection, recently, and individuals with congenital rubella infection and Seto.

An estimated 500,000 United States citizens are at risk against rubella infection. The following are the following concerns for a serious concern for other congenital rubella infection by Horst.

Cyton responsible for the following may be

5. Retarded fetal growth.
6. Hematologic changes, including thrombocytopenia and anemia.
7. Hepatosplenomegaly and jaundice.
8. Chronic diffuse interstitial pneumonitis.
9. Osseous changes.
10. Chromosomal abnormalities.

Infants born with congenital rubella may shed the virus for many months and thus be a threat to other infants, as well as to susceptible adults who come in contact with the affected infants.

Although the likelihood of major malformations at birth from rubella is relatively slight if it is acquired after the first trimester, the infants whose mothers contracted the disease after the first trimester will not necessarily be healthy as demonstrated by the investigations of Hardy and associates (1969). Their long-term prospective epidemiologic inquiry to assess the impact of the extensive 1964 rubella epidemic in this country revealed 24 instances of serologic evidence of infection by rubella virus after the first trimester. Of the 22 liveborn infants, only 7 could be considered completely normal when followed for periods of up to 4 years. Townsend (1975) and Weil (1975) and their associates have reported progressive panencephalitis beginning in the second decade in children with congenital rubella infection. Even more recently, an unusually high incidence of juvenile diabetes has been identified among individuals who had congenital rubella (Rayfield and Seto, 1978).

An estimated 14 million children in the United States have not been vaccinated against rubella. Moreover, there is cause for concern regarding the duration of immunity following immunization. The possibility exists for a major rubella epidemic and its disastrous consequences for the affected fetus. Further consideration of the problems for the obstetrician posed by rubella are provided by Horstmann (1979).

**Cytomegalovirus Disease.** The virus responsible for cytomegalic inclusion disease may be harbored in the genital or urinary

tract or both by a healthy mother and transmitted to the fetus across the placenta or during passage through the cervix and lower reproductive tract, or it may be harbored by the infant who ingests the virus in breast milk. Cytomegalovirus disease in the infant may cause hydrocephaly, microcephaly, microphthalmia, seizures, encephalitis, blindness, hepatosplenomegaly, and hematologic changes including thrombocytopenia and hemolytic anemia. At autopsy, cytomegalic inclusion bodies may be found in many organs of the body. The virus usually can be isolated in tissue culture of human cells. There are different antigenic types of the virus.

Although about 12 percent of women excrete the virus in urine or from the cervix during pregnancy and are likely to excrete the virus in their milk, few have offspring that are afflicted. Most often, a primary maternal infection seems necessary for the virus to be transmitted to and replicate in the fetus. Since primary infection is usually asymptomatic in the mother or, rarely, causes a mononucleosis-like syndrome, the disease is seldom suspected. Alford and co-workers (1974) emphasized that mental and auditory dysfunction occurs frequently enough to place this entity among the leaders of prenatal insults that induce developmental disability. No effective therapy for mother or infant is available. Cytomegalovirus disease seldom recurs in subsequent fetuses of the mother of one so afflicted.

**Varicella.** Varicella infections seem to be made worse by pregnancy. Varicella pneumonia, while very uncommon, is a grave illness during pregnancy, with high maternal mortality (Mendelow and Lewis, 1969; Pickard, 1968). Varicella may infect the embryo and fetus by transplacental passage of the virus. It may prove to be teratogenic when the embryo or fetus is infected (De Nicola and Hanshaw 1979). The virus may be acquired by the fetus in utero or during the course of delivery. Exposure to the virus just before delivery poses the greatest risk. If the baby is delivered before receiving varicella antibody from the mother, he may develop dis-

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acid elution principle described by Kleihauer, Brown, and Berke, or any of several modifications. Very small volumes of red cells commonly escape from the intravascular compartment of the fetus across the generally intact placental "barrier" into the maternal intervillous space. Although the bleed is usually small, it may incite maternal isoimmunization, as discussed below. Interestingly, evidence of maternal to fetal bleeding is very much less common (Bernard et al., 1977). Presumably a pressure gradient which is higher on the fetal than on the maternal side persists across the placenta.

Rarely, fetal to maternal hemorrhage may be so severe as to kill the fetus. The hypovolemic or severely anemic fetus-infant may be salvaged if the condition is recognized and treatment with blood, red cells, or both is promptly initiated. The fetus who is severely anemic is more likely to demonstrate one or more ominous heart rate patterns (see Chap. 14, p. 357). On occasion, the hemorrhage may have been chronic and so severe as to produce evidence of iron deficiency in the fetus (Pritchard and Cunningham, unpublished data). Maternal iron deficiency, however, even when severe, is not accompanied by anemia in the fetus; the same holds true for megaloblastic anemia due to folate deficiency (see Chap. 28, p. 720).

With large fetal to maternal hemorrhage there is most likely a placental lesion which fostered the leak. Chorioangiomas have been identified. Moreover, we know of two instances of severe fetal to maternal hemorrhage in which the mothers were later found to have choriocarcinoma. While neither placenta was studied, the subsequent recognition of choriocarcinoma in the mothers is suggestive that there was a placental lesion which was the site of transfer of blood from the fetus to the mother. Abruptio placentae, in our experience, does not appear to lead commonly to severe fetal to maternal hemorrhage.

At Parkland Memorial Hospital, for some time, maternal blood has been investigated for fetal red cells in each instance of stillbirth whenever a cause was not readily apparent.

Massive fetal-maternal bleeds have been identified in a very small minority of stillbirths.

Large fetal to maternal hemorrhages may also prove dangerous to the mother. It is possible for up to 400 ml of fetal blood to be transferred from the fetal-placental circulation into the maternal circulation. A transfusion reaction may then develop in the mother whenever A or B antigen is present in fetal red cells but not the red cells of the mother. Bergin and associates (1978), for example, have described many of the characteristic features of a transfusion reaction developing in a mother who was blood type O immediately after delivery of an infant who was blood type B. The subject of fetal-maternal hemorrhage has been reviewed by Renaer and associates (1976).

#### HEMOLYSIS FROM MATERNAL Rho (D) ISOIMMUNIZATION

Ranking as major contributions to medicine are the delineation of the pathogenesis of most cases of hemolytic disease in the fetus and newborn infant by the observations especially of Levine and associates (1941), the related discovery of the Rh factor by Landsteiner and Wiener (1940), and the development of effective maternal prophylaxis by Freda, Gorman, and Pollack (1963) in the United States and Finn, Clarke, and associates in Great Britain (1961).

**Blood Group Factors.** Originally, the Rh concept was extremely simple, defined by one antiserum and two blood group factors, namely Rh positive and Rh negative. The Rh factors, however, have become increasingly complex, and a host of other red cell antigens have been identified. Although some of them are immunologically and genetically important, fortunately, many are so rare as to be of little clinical significance in the genesis of erythroblastosis fetalis.

Any person who lacks a specific red cell

antigen most likely will create an antibody when exposed to that antigen. The antibody may prove harmful to the individual in case of a blood transfusion or to her fetus when she conceives. The vast majority of human beings have at least one such factor inherited from their father and lacking in their mother. In these cases, the mother could be sensitized if enough erythrocytes from the fetus were to reach her circulation and an immune response were to be stimulated by the foreign antigen. In these terms, hemolytic disease is a possibility in nearly every pregnancy. That the disease occurs in very few pregnancies is a result of several circumstances. These include (1) the varying rates of occurrence of the offending red cell antigens, (2) their variable antigenicity, (3) insufficient transplacental crossing of antigen from fetus to mother, (4) the variability of maternal response to the antigen, and (5) lack of transfer of antibody across the placenta from mother to fetus in amounts sufficient to affect the fetus.

The Rh antigens are inherited independent of all other blood group antigens. There is apparently no difference in the distribution of the various Rh antigens with regard to sex. There are, however, important racial differences. American Indians and Chinese and other Asiatic peoples are almost all Rho (D) positive (99 percent). Among black Americans there is a lesser incidence of Rho negative individuals (7 to 8 percent) than among white Americans (13 percent). Of all racial and ethnic groups studied thus far, the Basques show the highest incidence of Rho negativity (34 percent).

At times, hemolysis in the fetus involves other antigen-antibody interactions, especially the ABO system. These are considered subsequently. *All pregnant women should be routinely tested for the presence or absence of Rho (D) antigen in their erythrocytes and for irregular antibodies in their serum, including anti-Rho*

**Mortality.** The number of perinatal deaths from Rho hemolytic disease has dropped dramatically for the following reasons:

1. Pregnant women who are Rho negative and possess antibody to the Rho antigen can be readily identified.
2. Hemolysis in the fetus of the sensitized Rho negative woman can be predicted with considerable accuracy by the identification of abnormally high levels of bilirubin in the amniotic fluid.
3. The fetus who is most likely to be seriously affected can be treated by intraperitoneal transfusions of Rho negative red cells, or be delivered preterm before he expires in utero, or both.
4. Of greatest importance, the appropriate administration to the mother who is Rho negative of Rho immune globulin during or immediately after pregnancy has eradicated most, but not all, Rho isoimmunization among Rho negative women!

The favorable impact on reducing perinatal mortality as the consequence of these procedures is exemplified by the experiences in Manitoba. In that Canadian province, the number of perinatal deaths from hemolytic disease decreased from 29 in 1964 to zero in 1974 and one in 1975 (Bowman et al. 1977).

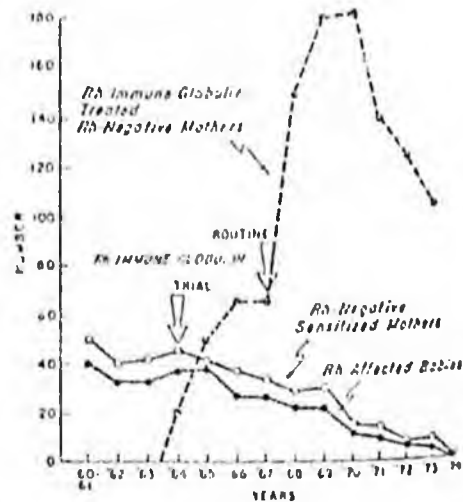


FIG. 38-1. Incidence of Rh disease correlated with Rh immune globulin treatment. (From Friedman et al. *N Engl J Med* 292:1014, 1975)

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\* Rho (D) (IgG) plasma provides immunog

### Immune Globulin Prophylaxis for the Rho (D) Negative, Nonsensitized Mother.

Hemolytic disease of the fetus and newborn from Rho (D) isoimmunization has become a problem almost totally limited to Rho negative women who were sensitized before Rho (D) immune globulin\* was available. Freda and co-workers (1975) summarized their 10 years of clinical experience with Rho immune globulin, confirming their original observations that such immune globulin given to the previously unsensitized Rho negative woman within 72 hours of delivery is highly protective, although not absolutely so (Figs. 38-1 and 38-2). There is good evidence to support the practice of giving the immune globulin promptly to previously unsensitized Rho negative women who have aborted including ectopic pregnancies and possibly hydatidiform moles, to women who undergo amniocentesis, and to those who bleed vaginally during pregnancy. The observation of Blajchman and co-workers (1974) of detectable fetal-maternal hemorrhage after at least 6 percent of amniocenteses has provided support for a policy that all unsensitized Rho negative women suspected of having an Rho positive fetus should receive Rho immune globulin following such a procedure. Freda (1973) has emphasized that when in doubt whether or not to give Rho immune globulin, the rule of thumb should be to give it.

While adherence to the above guidelines, including the administration of Rho immune globulin to the apparently nonsensitized mother within the first 72 hours after delivery of a Rho positive infant, has dramatically decreased the risk of maternal isoimmunization, the problem has not been eliminated. For example, Bowman and Pollock (1978) identified 1.8 percent of women to become isoimmunized in spite of adherence to the above recommendations for administering Rho immunoglobulin. He and his colleagues de-

\* Rho (D) immune globulin is a 2S immune globulin (IgG) extracted by cold alcohol fractionation from plasma containing high titered Rho antibody. Each dose provides not less than 300 µg of Rho antibody as determined by radioimmunoassay.

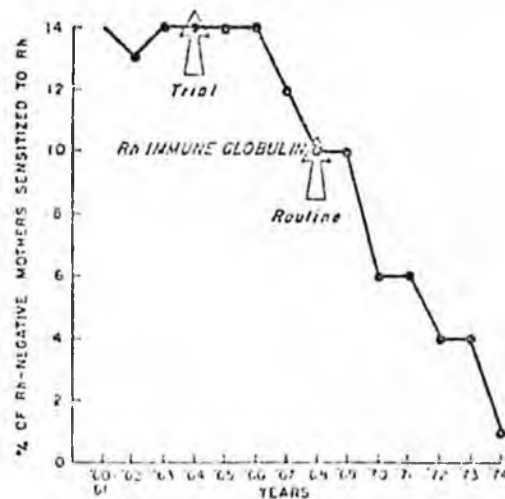


FIG. 38-2. Incidence of sensitization as a percentage of the total number of Rh-negative mothers seen per year. (From Freda et al. *N Engl J Med* 292:1014, 1975)

duced that most often the failures were the consequence of spontaneous silent fetal-maternal bleeds that occurred some time before delivery and therefore some time before the administration postpartum of Rho immune globulin. Therefore, to try to avoid isoimmunization from fetal-maternal bleeds that occurred remote from term, he administered routinely 300 µg intramuscularly to all nonsensitized Rho negative women at 28 weeks, and again at 34 weeks gestation, as well as at the time of amniocentesis or uterine bleeding. If the infant was Rho positive, a third dose of the immunoglobulin was administered to the mother after delivery. This program was followed by a reduction in the incidence of development of Rho isoimmunization during pregnancy from 1.8 percent to 0.07 percent. A single dose at about 28 weeks proved to be almost as effective as did the two doses antepartum; only 2 of 1799 Rho negative women showed evidence of Rho immunization, despite antenatal prophylaxis (Bowman and Pollock, 1978).

The small amount of antibody that crossed the placenta resulted at times in a weakly positive direct Coombs' test on cord and infant

blood. None of the infants, however, showed evidence of anemia or exaggerated hyperbilirubinemia.

**RECOMMENDATIONS.** A single intramuscular dose of 300  $\mu$ g of Rho immunoglobulin is administered routinely to all Rho negative, *nonimmunized* women at 28 to 32 weeks of gestation and again within 72 hours of the birth of a Rho (D) positive infant. A similar dose is also given at the time of amniocentesis and whenever there is uterine bleeding, unless the routine dose at 28 to 32 weeks had been given very recently. If a massive fetal-maternal hemorrhage is recognized, more immune globulin should be given, as described below. One dose of 300  $\mu$ g will protect the mother against a bleed of up to 15 ml of Rho positive red cells. Adoption of these dosage schedules should reduce the incidence of maternal isoimmunization to essentially zero.

#### ADVERSE MATERNAL REACTIONS

Only rarely do reactions occur after the intramuscular injection of commercially available Rho immunoglobulin. Usually the individual is IgA deficient and has previously developed an antibody to IgA. The Rho immune globulin that is currently available is likely to contain a small amount of IgA (Bowman, 1978). Rho immune globulin suitable for intravenous use very likely will become available.

**MATERNAL-FETAL BLEED.** Rarely, the Rho negative woman will have been exposed in utero to Rho antigen from her mother and become sensitized as the consequence. For this to occur, the woman's mother must have been Rho positive and a maternal-fetal bleed must have occurred sometime before the cord was severed. As with fetal-maternal bleeds, a major blood group (ABO) incompatibility most often appears to offer appreciable protection against Rho sensitization. Jen-

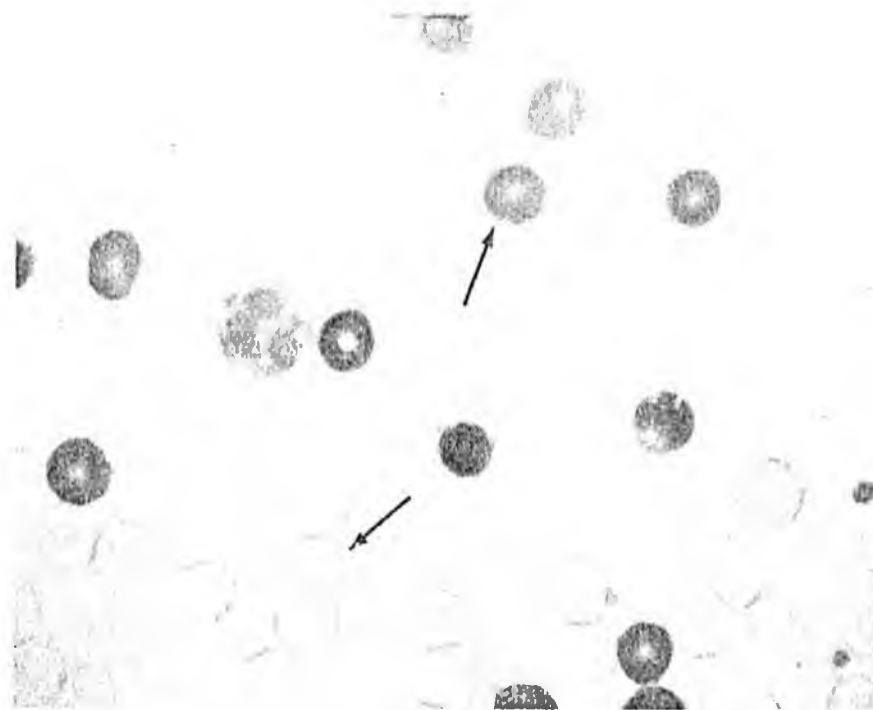


FIG. 38-3. Massive fetal to maternal hemorrhage. After acid elution treatment, fetal red cells rich in hemoglobin F stain darkly (upper arrow) whereas maternal red cells with only very small amounts of hemoglobin F (lower arrow) stain lightly.