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CRITERIA FOR STAFF IMPLEMENTATION OF "BACKFITTING" REQUIREMENTS FOR GASEOUS DIFFUSION PLANTS, NOTICE OF AVAILABILITY

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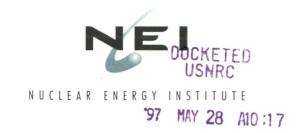
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OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH Marvin S. Fertel

VICE PRESIDENT, SUPPLIERS, INTERNATIONAL & FUELS

May 27, 1997

Mr. John C. Hoyle Secretary U.S. Nuclear Regulatory Commission Washington, DC 20555-0001

PROPOSED RULE 11 MISC (62 FR 14456)

2

ATTENTION: Docketing and Service Branch

SUBJECT: Request for Comments on "Criteria for Staff Implementation of "Backfitting" Requirements for Gaseous Diffusion Plants" 62 FR 14456

Title 10 CFR, Section 76.76 governs backfitting of gaseous diffusion plants (GDPs) certified by the Nuclear Regulatory Commission (NRC). By Federal Register notice dated March 26, 1997, (62 FR 14456) NRC solicited public comment on Office of Nuclear Material Safety and Safeguards (NMSS) Policy and Procedures Letter 1-53, which describes the procedures to be used to implement this section. The Nuclear Energy Institute¹ (NEI) is pleased to provide the comments below and in the attachment to this letter.

NEI submitted a petition for rulemaking on September 30, 1996, which would revise 10 CFR Part 70 to add a provision governing backfitting of fuel fabrication and enrichment facilities (among other changes). The backfit provision included in our petition is similar to 10 CFR 76.76. NEI therefore expects that the procedures described in NMSS Policy and Procedures Letter 1-53 will become the basis for backfit controls for Part 70 licensees once our petition has been adopted.

NEI's comments reflect this broader potential applicability even though NMSS Policy and Procedures Letter 1-53 is inherently applicable to only one entity. (Since



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¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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Mr. John C. Hoyle May 27, 1997 Page 2

the only two GDPs subject to Part 76 are operated by the U.S. Enrichment Corporation, USEC). USEC is one of NEI's member companies, and NEI has coordinated with USEC in preparing the comments herein.

NEI considers that good public policy requires that NRC establish a consistent and stable regulatory process for its licensees and certificatees. The backfitting provisions of section 76.76 are a commendable step in that direction. The provisions of the rule would limit changes to be imposed on GDPs to those which would provide a substantial increase in safety and for which the safety benefit would justify the implementing costs. However, as described in the attached comments the provisions of NMSS Policy and Procedures Letter 1-53 undercut the stability promised by the rule by inappropriately lowering the threshold at which backfits may be imposed. This appears to result from a conclusion that the radiological public health risk posed by the GDPs is small enough that it would justify few backfits. NEI agrees with this conclusion, and considers that it also reflects the overall risk situation from other fuel fabrication and enrichment facilities. This conclusion should lead to a highly stable regulatory regime, i.e., few backfits, rather than a redefinition of criteria to allow for more widespread changes.

NEI would be pleased to discuss these comments and to respond to any questions the NRC may have.

Sincerely,

Marvin S. Fertel

Man & toles

Vice President

Suppliers, International & Fuels

Attachment

NEI Comments on NMSS Policy and Procedures Letter 1-53

- 1. The combined effect of these procedures is to inappropriately lower the threshold for justifying imposition of a backfit. This results from explicit changes (e.g., use of "net benefit" rather than "substantial increase") and implicit changes, principally the procedure's emphasis on qualitative analysis. This emphasis is ostensibly caused by difficulties in quantifying safety benefits of changes at gaseous diffusion plants (GDPs). NEI considers that these difficulties can and should be overcome. The effect of a shift to a qualitative basis is to reduce the analysis to one of "we think it should be done" rather than a demonstration of clear safety enhancement. This is counter to the emphasis on quantitative analysis in NUREG/BR-0058, Rev. 2, "Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission" which is used as a basis for analyzing backfits for reactor licensees and is a principal reference of NMSS Policy and Procedures Letter 1-53. Lower radiological risk from GDPs and other fuel fabrication and enrichment plants than from reactors should justify a higher, not lower, threshold and a rigorous analytical process for imposed change. Specific comments in this regard are:
 - a. The procedure states that "the risk associated with enriched uranium exposure is primarily chemical toxicity, not radiological." NRC should apply the \$2000 per person-rem value of NUREG/BR-0058, Rev. 2, to quantifying the safety benefit of changes that are intended to reduce radiological exposures.
 - b. The procedure recommends that the staff use the "net benefits" approach discussed in NUREG/BR-0058, Rev. 2, to address the "substantial increase" standard of the rule. This is inappropriate. The rule clearly specifies that changes may only be imposed (except for certain specified circumstances) if they will result in "a substantial increase in the overall protection of the public health and safety or the common defense and security". A net benefit merely indicates that the monetized benefit is greater than the expected costs. It does not, and cannot, provide any information regarding the magnitude of the improvement sought. A minor benefit which can be achieved at very little cost would satisfy a net benefits test, but would clearly not meet the substantial increase test of the rule. This office procedure can not so change the clear language of the rule.
 - c. Section III.B.5 of the procedure, in discussing quantification of costs and benefits, states, "Use information to the extent that it is reasonably available. Make a qualitative assessment of benefits in lieu of a quantitative analysis if it will provide more meaningful insights or will be the only analysis practicable." Appendix 3 of the procedure later states that the staff will use a "qualitative non-monetary methodology" to derive benefits. It thus appears that quantitative analyses have been judged to be impracticable for any use.

These provisions should be revised. The bias should be in favor of requiring quantitative analysis, as it is in NUREG/BR-0058, Rev. 2.

- d. Appendix 3 to the procedure lists a number of factors which may be used to assess the "substantial increase" of a proposed benefit or modification. Several of these factors have tenuous, if any, connection to safety. For example, "greater uniformity of practice" may reflect a desirable outcome, but it is related to facility management rather than safety. Also, "fewer exemption requests and interpretative debates" may make the regulator's job easier, but this has no connection to a substantial increase in safety.
- e. The procedures discuss changes which may be imposed for worker safety (e.g., sections II.C.1.a.(2) and III.B.5.b). Improvement of worker safety is not cited in 10 CFR 76.76 as a basis for imposing a backfit. NRC staff can not expand the scope of the rule in these implementing procedures. Worker safety is recognized as important, but it is the principal responsibility of other agencies (e.g., Occupational Safety and Health Administration, OSHA) and should not be a basis for NRC-imposed regulatory requirements. (In this regard, it should be noted that the procedure itself is internally inconsistent. Section II.C.1.a.(2) refers to, "a backfit that is necessary to ensure that the plant presents no undue risk to worker and/or public health and safety/safeguards, as described in Section II.B.1.c.(4). The referenced section does not describe worker safety as a basis for a backfit).

Analyses performed under this procedure will be used to justify imposing changes on facilities which have a long history of safe operation. As such, it is appropriate that the threshold for requiring such change be high and that the NRC staff bear the burden of demonstrating that the threshold is exceeded.

- 2. 10 CFR 76.76 requires that "potential impact on radiological exposure of facility employees" be considered in evaluating whether a proposed backfit will produce a substantial increase in safety. Section III.B.5.b of the procedure states that "[t]he potential impact on radiological and/or chemical exposure of plant employees" should be considered. This expansion beyond the rule's scope is inappropriate. Protection against chemical hazards, per se, is outside NRC's regulatory jurisdiction. It is the responsibility of other agencies (e.g., OSHA). NEI considers that it would be appropriate to consider the effect on chemical safety in addition to radiological safety when quantifying the benefits of proposed backfits, but that it would be outside the agency's legislative mandate for NRC to require changes based solely on chemical risks.
- 3. The procedures intermix "commitments" with requirements and staff positions as vehicles by which backfits may be imposed. The term commitment is used in 10 CFR 76.76 only in the context of assuring compliance with existing written commitments. A commitment is, by common definition, an action to which a

licensee/certificatee has agreed voluntarily. A commitment is not a vehicle which can be used by NRC to impose requirements. The procedure should be revised to remove discussion of commitments in that context.

- 4. Section II.A.1.a states, "For any proposed staff position, the staff must question whether it is directing, telling or coercing rather than merely suggesting or asking that the certificatee consider an action." The industry encourages open communications with the NRC and support any dialogue that is aimed at improving safety at our facilities. However, the staff should be required to explicitly identify suggested actions as non-mandatory in any communication with the certificatee. The certificatee should be free to accept or reject any suggestions without need to defend this action before the staff. Otherwise, suggestions become coercion. In any case in which the certificatee declines to accept an NRC "suggestion", the staff is free to impose the suggested change if it can be justified as a backfit under 10 CFR 76.76.
- 5. The procedure uses the combined term "safety/safeguards" at several places (e.g., II.B.1.c.4, III.B.3). This combination of concepts is inappropriate:
 - a. Most of these references relate to circumstances in which the staff determines that a backfit is required to ensure "no undue risk to public health and safety/safeguards", and thus no regulatory analysis is required. The rule provides an exception for actions necessary to ensure "that the plant provides adequate protection of the health and safety of the public and is in accord with the common defense and security" (10 CFR 76.76.(a).(4).(ii)), but this exception does not relate to safeguards. Changes required to ensure compliance with existing safeguards requirements would be exempted from analysis under 10 CFR 76.76.(a).(4).(ii) as "necessary to bring a plant into compliance", but this exception has nothing to do with adequate protection (or undue risk). The concept of "undue risk to ... safeguards" goes beyond the rule and should be deleted.
 - b. Section III.B.3. uses the combined term in a different context. Here, regulatory analyses are required to "[d]etermine the potential impact on safety/safeguards". The rule does not provide for backfits which improve safeguards. Since such impacts may not be used to justify backfits, regulatory analyses of proposed backfits should not consider impact on safeguards.
- 6. Implementation deadlines should be tolled during the review of backfit claims by a certificatee unless immediate implementation is needed to assure safety. If deadlines are not tolled, delays in staff review of backfit claims could render the claim moot. Engineering, procurement and planning may have to occur to assure that the required deadline is met, even in cases where the deadline appears to be comfortably in the future. To prevent the imposition of inappropriate burden

(which would clearly be the case should the certificatee claim be upheld) tolling should be on a day-for-day basis during the pendency of the claim.

- 7. Appendix 4 provides that "Application of SRPs [standard review plans] to an operating plant or plants after the certificate is granted generally is considered a backfit unless the SRPs were approved specifically for operating plant implementation and are applicable to such operating plant or plants, or SRP guidance is applied in a review of certificatee-proposed modification to its current certification basis." Since no approved SRPs currently exist covering GDPs, imposition of provisions from any SRP would be a backfit. In the case of other licensees which could be covered by similar procedures once NEI's petition for rulemaking is accepted, the exception covering use of SRP guidance for (in that case) licensee-proposed changes must be limited to the scope of the licensee proposal. Imposition of other provisions of an SRP, which do not relate directly to a licensee proposal, would still be a backfit.
- 8. Appendix 4 notes that imposition of future regulatory guides may not be a backfit. It goes on to say that, "[t]hese regulatory guides go through NRC's public review and comment process before staff implementation of these guides." NEI notes that this process does not mean that new guides do not represent backfits. Imposition of a new regulatory guide which interprets an existing rule in a manner which requires a change to the facility or procedures at a plant would still meet the rule's definition of a backfit regardless of the public comment process. We presume that generic imposition of the position in any new regulatory guide would be considered during the development and approval of the guide. This consideration must meet the provisions of the backfit rule.
- 9. NEI notes that the USEC comments on these procedures take issue with the baseline from which the backfit rule applies. This issue derives from the fact that the GDPs have not historically been regulated by NRC, and that the requirements governing their operation were not developed originally by NRC. NEI supports the USEC position on this issue. We note that this issue is unique to the GDPs. If a backfit provision is added to Part 70, as proposed by our petition, and similar procedures are used to implement that provision, the baseline would be the existing licensing basis for each licensee, that has been developed and imposed by NRC.
- 10. NMSS Policy and Procedures Letter 1-53 applies only to NMSS personnel. The rule applies to the agency as a whole. The procedures described in this letter, once revised as discussed above, should be promulgated in a manner which makes them applicable to all NRC personnel involved in regulation of the GDPs, at headquarters and in the Region.

DOCKETED USNRC

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SERIAL: GDP 97-0084

May 27, 1997

PROPOSED RULE MISC (62 FR 14456)

Secretary

United States

Enrichment Corporation

US Nuclear Regulatory Commission Washington, D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Paducah Gaseous Diffusion Plant (PGDP)
Portsmouth Gaseous Diffusion Plant (PORTS)
Docket Nos. 70-7001 and 70-7002
USEC Comments on "Criteria for Staff Implementation of 'Backfitting' Requirements for Gaseous Diffusion Plants," 62 Fed. Reg. 14456 (March 26, 1997)

Dear Sir:

On behalf of the United States Enrichment Corporation (USEC), I am pleased to provide comments on the NRC's Criteria for Staff Implementation of "Backfitting" Requirements for Gaseous Diffusion Plants for your consideration.

Attachment 1 includes both general and specific comments on the Policy Letter. Of primary significance are the following comments:

Concerning the Staff's application of the "Substantial Increase" standard (see USEC General Comment No. 1), USEC believes that the Policy Letter should be modified to make the expectation clear that backfits will be justified on the basis of <u>quantitative</u> analyses (including the \$2,000 per person-rem conversion factor) absent exceptional circumstances, and to eliminate the "net benefits" approach. These and other proposed modifications discussed in our comments would make the Staff's guidance consistent with NUREG/BR-0058, Rev. 2 and impose upon the Staff the same burden it has when doing cost/benefit analyses on other licensing or regulatory actions.

Concerning the Policy Letter's reference to plant modifications based on the Updated Safety Analysis Reports (see USEC General Comment No. 2), it remains USEC's position that the backfit provision included in Part 76 was intended to become effective and to be applied when the final 10 CFR Part 76 became effective, on October 24, 1994. Therefore, if, as a result of the DOE SARUP effort and/or USEC's amendment request, the NRC believes that additional changes in facilities, equipment,

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Rulemakings and Adjudications Staff May 27, 1997 GDP 97-0084 Page 2

TSRs, procedures, or organization are required beyond those proposed by USEC, such changes must be justified under the backfit rule.

As reflected in Attachment 1, USEC has fundamental concerns with the Policy Letter and we believe significant modifications are needed to bring the Policy Letter into conformance with applicable NRC regulations and existing Staff guidance documents before it is finalized and implemented by the Staff.

The Nuclear Energy Institute (NEI) is also providing comments to the NRC on the Staff's Policy Letter. USEC concurs with NEI's comments, which underscore and support our views.

We would be pleased to discuss these comments with you. Please contact me at (301) 564-3413 or Ms. Lisamarie Jarriel at (301) 564-3247.

Sincerely,

Robert L. Woolley

S.D. Rollfor

Nuclear Regulatory Assurance and Policy Manager

Attachment 1

COMMENTS ON NMSS POLICY AND PROCEDURES LETTER 1-53 GDP PLANT SPECIFIC AND GENERIC BACKETT MANAGEMENT

General Comments

- 1. Application of "Substantial Increase" Standard: Appendix 3 to the draft policy/procedure is entitled, "Guidance on Application of the 'Substantial Increase' Standard." It discusses the interpretation of the "substantial increase" standard in a manner which is not fully consistent with NUREG/BR-0058, Rev.2, Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission, (which it cites as a principal reference). It also inappropriately reduces the burden placed on the NRC Staff by NUREG/BR-0058 to justify a determination that a proposed backfit would provide a "substantial increase" in overall protection. Furthermore, it contains criteria which should not be considered in making the "substantial increase" determination. In particular:
 - (a) The "substantial increase" determination standard in 10 CFR § 76.76 states that except as provided elsewhere in the regulation:

The Commission shall require the backfitting of a plant only when it determines . . . that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that plant are justified in view of this increased protection.

NUREG/BR-0058, Rev. 2 references the \$2,000 per person-rem value used by the NRC for assessing the costs and benefits (and other regulatory actions) that are intended to reduce radiological exposures. Appendix 3 of the draft policy/procedure however, entirely dismisses the use of the \$2,000 per person-rem conversion factor as "not appropriate since the risk associated with enriched uranium exposure is primarily chemical toxicity, not radiological."

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There are, however, some radiological risks at the GDPs and to the extent that a proposed backfit is intended to address such risks, there is no basis for not employing the NRC's accepted tool for capturing the monetary worth of a given amount of radiation exposure. If the justification for a proposed backfit is based in whole or in part on radiological exposure considerations, there is no basis not to use the \$2,000 per person-rem conversion factor. If the NRC does not use that factor, it will be treating USEC differently than all other NRC licensees when there is no basis for such differences. Furthermore, the Staff should consider whether there is some other comparable measure of the relative value of the risk associated with exposures to chemical hazards of radioactive materials. For such chemical hazards, a linear no-threshold approach should not be utilized. If chemical toxicity is the predominant hazard and NRC regulatory actions will be focused on that hazard, failure to establish a quantitative measure similar to the \$2,000 person-rem value would make the NRC's cost/benefit analyses arbitrary and subjective.

(b) Instead of using the conversion factor, the policy letter recommends that the Staff use the "net benefits" approach, discussed in NUREG/BR-0058, Rev. 2, when addressing substantial increase under 10 CFR § 76.76. However, a "net benefit" is not necessarily equivalent to a "substantial increase," even in qualitative terms. In NUREG/BR-0058, Rev. 2, the Staff repeats the Commission's views (first expressed in the preamble to the 1985 10 CFR § 50.109 backfit rule) that "substantial" means important or significant in a large amount, extent or degree. In applying such a standard, the Commission would not expect that safety improvements would be required as backfits if they result in less than a significant benefit to the public health and safety regardless of cost. The "net benefit" standard prescribed in the policy letter does not meet the Commission's test that the proposed action increase public health and safety in an important or significant manner. This is further exacerbated by the inability to accurately calculate safety benefits. The use of the "substantial increase" test prevents expenditure of resources on changes resulting in trivial safety benefits. For example, a proposed action could result in little safety benefit but if the analyzed cost is also small, the proposed action could be shown to result in a "net benefit" resulting in the action being imposed on the GDP(s). Such a decision would violate

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the intent of the § 76.76 rule and potentially distract all involved from those issues of real safety significance.

- (c) In Appendix 3, the NRC Staff has also stated that it will use a "qualitative non-monetary methodology to derive the safety/safeguards benefit..." This does not appear to be consistent with NUREG/BR-0058, nor does it appear to place a sufficiently high burden on the NRC Staff to justify a finding that a proposed backfit will meet the "substantial increase" requirement. This represents a significant deficiency in the draft policy. Throughout NUREG/BR-0058, the NRC Staff has made it clear that quantitative analyses are much preferred over qualitative ones, even if values and impacts cannot be expressed in "monetary" terms (i.e., \$2,000 per person-rem). In particular, NUREG/BR-0058, Rev. 2 (pp. 20-21) states:
 - Estimated values and impacts should be expressed in monetary terms whenever possible;
 - Consequences that cannot be expressed in monetary terms should be . . . quantified in appropriate units to the extent possible;
 - For materials licensees] the staff needs to make every reasonable effort to apply alternative tools that can provide a quantitative perspective . . . concerning the value of the proposed action;
 - Even inexact quantification with large uncertainties is preferable to no quantification,
 - Where PRAs or other statistics-based analyses are not available] the generally recommended approach is to utilize whatever data may be available within a simplified model to provide some quantitative perspective;
 - Fig. [Where quantification is not possible,] reliance on the qualitative approach should be a last resort, to be used only after efforts to develop pertinent data or factual information have proven unsuccessful; [emphasis added] and
 - Certain issues, such as those involving emergency preparedness, security, and personnel requirements, tend to fall into [the] category [of issues requiring qualitative analyses].

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Contrary to the above statements, Appendix 3 of the draft policy letter broadly concludes, with no basis, that qualitative analyses will be used to assess any potential backfit at the GDPs, regardless of whether reasonable, quantitative data can be obtained and regardless of the nature of the backfit. Thus, proposed changes to emergency planning requirements will be treated in the same manner as proposed changes to areas where there may be considerable opportunity for quantification, such as accident analysis results. This is a significant departure from NUREG/BR-0058, Rev. 2 and it is not justified by the Staff. Its effect is to substantially and summarily reduce the reasonable burden on the NRC Staff to base proposed backfits on quantifiable ground where it is practicable to do so. Furthermore the guidance in Appendix 3 is so general that it is our belief that it would be very difficult for the Staff to assure any degree of consistency in the preparation of regulatory analyses when relying on qualitative arguments. This could create, at least, the perception that the decision making process is "arbitrary and capricious." Despite the cautions in the NUREG that analyses of this sort should be subject to a higher level of scrutiny because of the degree of judgement involved, the policy letter suggests no such process.

(d) NUREG/BR-0058, Rev. 2, Section 4.3.2, "Estimation of Impacts" describes the steps that must be taken when the analysis of the impact on the license results in costs that are so high that fluture operations are not economically feasible. Because of the age and nature of the GDP design, there are many possible new regulatory demands for which the cost impact could be so severe that they would threaten GDP economic viability.

The GDPs have accumulated over 125 plant-years of safe operation. Existing accident analyses do not demonstrate a high public health and safety or environmental risk. NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," concludes that the potential public radiological threat associated with similar facilities is less than that of reactors. So while it is hard to imagine that there could be an issue of such safety importance that its implementation is absolutely necessary at whatever the cost, we are concerned that the proposed reliance on qualitative analysis does not provide an adequate consideration of these issues. The issue

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of premature facility closure forced by a backfit should be addressed in the Staff's guidance.

(e) USEC does not agree that the "example" cited in Appendix 3 properly justifies the use of qualitative analyses. In particular, the Appendix states:

[T]he incorporation of industry standards (including revisions to existing codes and standards) into NRC rules or staff positions . . . can provide the basis for a finding that a proposed backfit meets the "substantial increase" standard . . .

Maintenance of compliance with voluntary industry standards is an important good practice and specific versions of such standards are often committed to by a licensee or certificatee in regulatory documents. When a new or revised standard is issued, however, the changes do not necessarily provide a "substantial increase" in safety or security, nor is it certain that for a particular facility such changes are cost-justified. If the example is intended to mean that the mere existence of a code or standard revision warrants a backfit and demonstrates that a "substantial increase" in protection would be provided by the backfit, we do not agree.

(f) Finally, Appendix 3 lists nine "[a]dditional factors" that may be used to assess the "substantial increase" standard. Several of these appear irrelevant or at best only tangentially related to the important finding which the NRC must make to justify a backfit. It is not at all clear, for example, how "[g]reater uniformity of practice" or "[f]ewer exemption requests and interpretative debates" would be relevant to a determination by the NRC that a backfit would provide a "substantial increase" in safety or common defense and security. We have similar reservations about factor 4 ("[g]reater specificity in existing generally-stated requirements") and factor 6 ("[g]reater confidence in the reliability and timeliness of information or programs").

Recommendation: Appendix 3 should be modified to be consistent with NUREG/BR-0058, Rev. 2 and to: 1) impose upon the Staff the same burden it has when doing cost/benefit analyses on other licensing or regulatory actions, by making the expectation clear that backfits will be justified on the basis of quantitative analyses absent exceptional circumstances, 2) confirm that the \$2,000 per

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person-rem conversion factor applies, 3) define a similar standard for chemical exposures from radioactive materials, 4) address the issue of premature facility closure forced by a backfit, and 5) better define guidance to the Staff for applying qualitative methods when necessary.

2. Plant, Procedure or Organizational Modifications Based on the Updated Safety Analysis Reports (SARUP): Appendix 4 to the policy letter, "Guidance for Backfit Determinations," states on page 4 that:

The staff's review and comments on the updated SAR, as committed by the Certificatee in Issue 2 of the Compliance Plan, is a compliance issue and is <u>not</u> considered a backfit.

USEC would like to clarify its understanding of both this specific statement and its relationship to our overall interpretation of the backfit rule.

Compliance Plan Issue 2 entitled, "Update the Application Safety Analysis Report," was written to document and address the fact that the existing Safety Analysis Reports (SAR) require updating and revision to include the results of the DOE SARUP effort. USEC is required to update and revise the SARs and to propose any associated changes to the plant facilities, equipment, Technical Safety Requirements (TSRs), procedures, and organization in its August 17, 1997 certification amendment.

If, as a result of the DOE SARUP effort and/or USEC's amendment request, the NRC believes that additional changes in facilities, equipment, TSRs, procedures, or organization are required, such changes must be justified under the backfit rule. Such unidentified future changes may not be encompassed by the existing Compliance Plans; and the backfit rule applies and requires appropriate justification of such changes before their imposition. This is the case because the backfit provision included in Part 76 was clearly intended to become effective and to be applied

It should be noted that the following statement in the Staff's Compliance Evaluation Reports appears to state a contrary position: "[s]ince the SAR Upgrade is required to achieve compliance with NRC requirements, any safety improvements called for by the SAR Upgrade would not be subject to the backfit provisions in 10 CFR 76.76. PGDP CER, p.118; PORTS CER, p.131.

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when the final 10 CFR Part 76 became effective, on October 24, 1994. The basis for this interpretation is provided in the attached paper, "Analysis of Applicable "Baseline" for Purposes of Backfitting Rule (10 CFR § 76.76)."

<u>Recommendation</u>: The words, "... at the time of the initial certification" in Section I.B of the policy letter should be modified to read, "... when Part 76 became effective on October 24, 1994."

3. Chemical Hazards: 10 CFR § 76.76 requires that the "potential impact on radiological exposure of facility employees" be considered in the evaluation of whether there is a substantial increase in the overall protection of the health and safety of the public. Section III.B.5.b, page 10, of the policy letter, however, states that the regulatory analysis for a proposed backfit should address the "potential impact on radiological and/or chemical exposure of plant employees." Regulation of hazards associated with or derived from non-radiological materials is beyond the NRC's regulatory jurisdiction and the language of the policy letter is not consistent with the regulation.

<u>Recommendation</u>: The policy letter should be modified to comply with the rule. Furthermore, in light of the general purpose of the backfit analysis, the review of the impact to workers should consider the *change* in exposure as a result of the backfit when compared to applicable impacts already considered in the certification basis.

4. Policy Letter Scope: The policy letter appears to only apply to NMSS Staff personnel. For example, Section II.A states that "NMSS staff is responsible for identifying proposed backfits." The policy letter does not impose similar requirements on the Regional Staff which will originate and issue its own regulatory correspondence.

Section IV.B. describes the appeal process and states that the certificatee may appeal to NMSS "even if the backfits were denied or decided by the region." However, the policy letter does not contain provisions for the Regional Staff to deny or decide a backfit appeal.

Recommendation: A policy document that implements the backfitting provisions of 10 CFR § 76.76 for both Regional and Headquarters Staff should be developed.

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Specific Comments

Definitions, Section I

1. Section II.A, Identifying Backfits: Although a distinction between plant specific and generic backfits is made in the definition section of the policy letter, the guidance itself does not make a clear distinction. Section II.A refers to the process of identifying backfits in "generic communications" and requires the review and approval of such communications by the Director, NMSS prior to issuance. This differs from the process followed by the Staff when issuing other generic communications, such as Bulletins and Generic Letters. In that case, additional review and approval is required by the Committee to Review Generic Requirements (CRGR). USEC believes that the process defined for identifying and implementing generic backfits should generally follow the process for plant specific backfits with the additional step of review and approval required by the CRGR.

Furthermore, since there are only two GDPs, the policy letter should require that any correspondence sent to USEC which requires a response be first reviewed for generic applicability before issuance. If generic, the process should require a backfit review and CRGR approval prior to issuance.

Recommendation: The Staff's backfit policy letter should be modified to specify that all correspondence to USEC regarding the GDPs, and requiring a response, be reviewed for generic applicability before issuance. If determined to be generic, the process should require a backfit review and CRGR approval prior to issuance.

2. Section II.A.2, Identifying Backfits, Certificatee Claims: The policy letter uses the term "commitment" to describe the proposed new requirements or newly imposed NRC Staff positions that may constitute a potential backfit. Use of the term in this manner does not seem to be necessary or appropriate. For example, in Section II.A.2 of the policy letter, the NRC Staff states "[a] certificatee may claim that a proposed requirement, commitment, or staff position is a potential

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backfit . . . " A potential backfit involves a new or amended rule or the imposition of a new Staff position. Commitments are made by the certificatee and until they are proposed for "imposition" by rule, order, or certification condition, they would not constitute a backfit. Therefore, the term "commitment" should not be used in this context.

Recommendation: Delete the term "commitment" from the policy letter in the following places:

- Page 1, Section I.C, Paragraph 1, Line 6,
- Page 2, Section II.A, Paragraph 1, Line 3,
- Page 2, Section II.A.2, Line 1,
- Page 3, Section II.B, Paragraph 1, Line 2,
- Page 3, Section II.B.1.c(3), Line 1 and Line 7,
- Page 7, Section II.C.1.b(1), Line 1,
- 3. Section II.C.1.a(1), When a Documented Evaluation is Used: This Section describes the information required to be documented by the Staff when it is determined that a modification is necessary to bring the plant into compliance with the certificate. The information is actually required by 10 CFR § 76.76(a)(6).

Recommendation: Change "should provide" to "must include" in Line 3 on the top of page 6 to be consistent with 10 CFR § 76.76(a)(6).

4. Section II.C.1.a(2), Backfits Identified by the Staff: The references to the worker in this section and Section III, page 9 and Section III.B.5.b, page 10, go beyond the language of 10 CFR § 76.76. The staff may not vary the terms of a regulation in an informal guidance document.

Recommendation: The policy letter should be modified to be consistent to the rule.

5. Section II.C.1.b(1)(b), When a Regulatory Analysis is Used: The policy letter suggests that the Staff may recommend improvements even when they do not meet the backfit test. It should be made very clear in such cases that the proposed improvement is only a recommendation and not

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required. It should also be clear that any "recommendations" that the certificatee considers a backfit would be subject to appeal, if necessary.

This same comment applies to Section II.C.2.b(1)(e), Backfits Identified by the Certificatee.

<u>Recommendation</u>: The policy letter should be modified to clearly distinguish between a Staff recommendation and an imposed requirement and ensure that the appeal process applies to both.

6. Section ILD, Information Requests: With respect to the review of amendment requests or recertification, the policy letter states that if information is part of the "standard procedures applicable to the review" analysis or justification for an information request is not necessary. It is unclear what the "standard procedures" are that are referred to in this section.

Recommendation: These "standard procedure" documents should be made available to the public so a complete understanding of this policy guidance can be realized.

7. Section II.D, Information Requests: The policy letter states that "... requests for information, including fact-finding reviews, inspections, and investigations of accidents or incidents to determine compliance with existing plant requirements are not considered within the scope of the backfit rule." It should be clarified that although these types of reviews in and of themselves do not constitute a backfit, they can result in new interpretations of existing plant requirements, they are, by definition, within the scope of the backfit rule. Section I B of the policy letter defines a backfit as "[a] modification of or addition to systems, structure, or components of a plant. . .any of which results from . . .the imposition of a regulatory staff position interpreting the Commission rules or a certificate commitment that is either new or different from a previous staff position."

<u>Recommendation</u>: The policy letter should be modified to clarify the statement in Section II.D that begins, "Moreover, requests for information including fact-finding reviews . . ."

8. Section II.D.1, *Information Requests*: The policy letter specifies that when the Staff is preparing and approving information requests to the certificatee, and the request requires an explanation, then

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a statement must be prepared to include, in part, a "description of the need for the information in terms of potential safety benefit."

<u>Recommendation</u>: When preparing the aforementioned explanation for the an information request, the explanation should also include the applicable regulatory requirements and references.

Regulatory Analysis, Section III

9. Section III.B, Regulatory Analysis: 10 CFR § 76.76 requires a "systematic and documented analysis pursuant to paragraph (b) of [76.76] for backfits which it seeks to impose." The elements of that analysis as defined in § 76.76(b) are for the most part included in Section III.B.1 through III.B.5 of the policy letter. As pointed out in USEC's General Comment No. 3, reference to the potential impact on the chemical exposure of plant employees in Section III.B.5.b should be deleted to comply with the rule. Similarly, it does not appear that the provisions of § 76.76(b)(8), namely the consideration of "... potential impact of differences in plant type, design, or age on the relevancy and practicality of the proposed backfit;" are addressed in the policy letter.

<u>Recommendation</u>: The policy letter should be modified to comply with the rule.

10. Section III.B.3, Regulatory Analysis: The wording in this section is not consistent with the rule.

Recommendation: In Section III.B.3, revise "potential impact on safety/safeguards" to "potential safety impact" to be consistent with 10 CFR § 76.76(b)(6).

Principal Mechanisms Used to Establish Communicate Staff Positions, Appendix 1

11. Appendix 1, Mechanisms Sometimes Used to Communicate Staff Positions: It is not clear what the difference is between "Unresolved issues resulting from inspections" on Page 2, and "Inspection Findings" on Page 3.

Recommendation: Delete "Unresolved issues resulting from inspections" on Page 2.

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12. Appendix 1, Mechanisms that Should Not be Used to Communicate Staff Positions: This Appendix lists mechanisms that should not be used to communicate legal requirements or staff positions. USEC believes NMSS Policy and Procedure Letters should be added to that list.

<u>Recommendation</u>: Add "NMSS Policy and Procedure Letters" to the list of mechanisms that should not be used to communicate staff positions.

Guidance on Backfit Determinations, Appendix 4

13. Appendix 4, Standard Review Plans: There is no approved Standard Review Plan (SRP) for the GDPs. Furthermore, the Certification Application was not written to or reviewed/approved against a SRP or similar document. There is no regulatory requirement for the GDPs to meet any SRP. Therefore, to base a review on any SRP requirement would, in itself, be a backfit.

Recommendation: All references to SRPs should be removed from the policy letter.

14. Appendix 4, Regulatory Guides: The section in Appendix 4 which discusses Regulatory Guides appears to imply that new or revised regulatory guides may not fall within the scope of the backfit rule. It should be clarified that fixture regulatory guides should be reviewed as potential backfits.

<u>Recommendation</u>: The policy letter should be modified to indicate that future regulatory guides are within the scope of the backfit rule.

15. Appendix 4, Regulatory Guides: It is not clear what is meant by the term "generic implementation determination."

Recommendation: Please explain the term "generic implementation determination" and its significance.

16. Appendix 4, Regulatory Guides: The second paragraph under Regulatory Guides suggests that a Staff action with respect to a specific certificatee is a "plant specific backfit." This appears in

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conflict with the definition of generic backfit in Section I.B where a generic backfit is defined as one that applies to two or more plants, regardless of whether more than one certificatee is involved. USEC believes that a generic backfit should be defined to be one that applies to two plants, without reference to the number of certificatees.

<u>Recommendation</u>: Replace the word "certificatee" with "plant" in the last line under Regulatory Guides so that the sentence reads, "... with respect to a specific plant that expands on ..."

Attachment 2

ANALYSIS OF APPLICABLE "BASELINE" FOR PURPOSES OF BACKFITTING RULE (10 CFR § 76.76)

L Introduction

A. 10 CFR § 76.76(a)(1) states:

Backfitting is defined as the modification of, or addition to, systems, structures, or components of a plant; or to the procedures or organization required to operate a plant; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a <u>previous</u> NRC staff position. (emphasis added.)

B. As currently written, this provision does not explicitly address what "baseline" applies for purposes of conducting backfits. In particular, may an NRC position or interpretation raised as part of the initial certification or Compliance Plan implementation process constitute a potential backfit?

II. Pre-Proposed Rule History

A. In SECY-93-285A (November 24, 1993) regarding the draft proposed 10 CFR Part 76, the NRC Staff had initially recommended the following language for section 76.76(a)(1):

Backfitting is defined as the modification of, or addition to, systems, structures, or components of a plant; or to the procedures or organization required to operate a plant; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from the staff position at the time of issuance of the first annual certification following the initial certification under this part. (emphasis added.)

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B. In explaining this provision, the Staff stated:

In recognition of Commission interest, the staff has further considered a backfit requirement in the proposed rule and concluded that such a provision could be included. However, because the staff has no experience with backfit provisions appropriate for the two gaseous diffusion plants, the backfit provision recommended by the staff in the rule reflects provisions contained in 10 CFR Part 50, with the baseline to be established after the first annual certification following the initial certification. Other options with respect to the baseline include the first certification, certification after several years, or even the existing plant configuration prior to the first certification. (emphasis added.)

- C. This draft provision would have established the first annual certification following the initial certification as the applicable "baseline."
- D. However, the words "at the time of issuance of the first annual certification following the initial certification" were excluded from the final version of proposed section 76.76, in accordance with the Commission's explicit directive in a Staff Requirements Memorandum (SRM) dated January 7, 1994, that "the backfit criteria should go into effect when the final rule goes into effect," (emphasis added.)
- E. The Commission's January 7, 1994 SRM was clearly intended to establish that plant, procedure, or organizational modifications or additions to the "existing plant configuration" which are necessitated by a new or different NRC Staff position would be subject to the backfit rule.
 - Had the Commission intended for NRC regulatory actions or positions prior to completion of the first certification or to the completion of a later certification decision to be exempted from backfit considerations, it would have provided some indication to that effect. No such indication exists.

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2. By simply directing the Staff to make the backfit provision effective "when the final rule goes into effect," the Commission intended to afford to USEC backfit protection as of that date.

III. Proposed Rule History

- A. In the Statements of Consideration accompanying the proposed Part 76, Commissioner Rogers sought comments on whether the provisions of section 76.76 should become effective immediately when 10 CFR Part 76 became final, as would happen were the proposed section to remain unchanged. 59 Fed. Reg. 6792, 6797-98 (February 11, 1994).
- B. USEC and DOE submitted comments stating that the provisions of section 76.76 should be made effective when the rule became final.
 - In endorsing the proposed backfit provision as written, USEC stated that "the backfit provision should apply to any plant changes necessitated by NRC rules or interpretations after Part 76 becomes final...."
 - 2. In stating that there was "no need to ... delay the effectiveness of § 76.76," DOE noted that it would "continue to give the NRC staff the full benefit of its experience in the oversight of gaseous diffusion plant operation during the past 40 years...."

IV. Final Rule History

- A. The NRC agreed with the above comments, and the final section 76.76 was left unchanged.
- B. In particular, in adopting the final rule, the NRC discussed Commissioner Rogers' inquiry as follows:

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Commissioner Rogers was particularly interested in ... [w]hether the provisions of § 76.76 should become effective immediately when 10 CFR Part 76 becomes final, as would happen were the proposed section to remain unchanged....

A number of commenters agreed that the provisions of § 76.76 should be made effective when the rule becomes final. There were no comments received in support of a delay in the implementation of the backfit provisions....

The final rule is unchanged.

V. History of Safe Operations

- A. If the GDPs had an unsafe operating history, it might then perhaps be reasonable to establish a backfitting baseline later that October 24, 1994. However, in several instances, the NRC and DOE have repeatedly acknowledged that the GDPs have operated safely for over 40 years, that Part 76 requirements are similar to applicable DOE requirements, and that the NRC simply intends to extend and rely upon the "existing DOE safety basis."
 - 1. The Statements of Consideration accompanying the proposed Part 76 state, in part:

The Commission recognizes that the [GDPs] were designed and constructed before the new certification requirement was established in the Energy Policy Act of 1992, and that they have operated safely for approximately forty years. This proposed rule is based upon comparable NRC requirements that have been in place for a number of years, and that the staff believes are adequate and appropriate for the [GDPs], and are at least as stringent as the DOE requirements under which the plants currently operate.

59 Fed. Reg. 6792 (February 11, 1994).

2. The Regulatory Analysis on the final 10 CFR Part 76 states, in part:

[The promulgation of 10 CFR Part 76] should have no significant impact on the public as there will be no change to the level of protection of public health and safety currently required for the plants by the Department of Energy (DOE). Certification will be mainly based on requirements which incorporate standards already used by NRC for regulating other nuclear fuel cycle activities of private industry, which are similar to safety practices used by DOE at its facilities.

PROPOSED RULE PR MISC (62 FR | 4456)

DOCKETED USNRC

[7590-91-P] MAR 26 A.8:43

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

NUCLEAR REGULATORY COMMISSION [DOCKET NOS. 70-7001; 70-7002]

CRITERIA FOR STAFF IMPLEMENTATION OF "BACKFITTING"

REQUIREMENTS FOR GASEOUS DIFFUSION PLANTS; NOTICE

OF AVAILABILITY

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability

SUMMARY: On March 3, 1997, the U.S. Nuclear Regulatory
Commission assumed regulatory jurisdiction over the Gaseous
Diffusion Plants (GDPs) from the U.S. Department of Energy. The
GDPs are regulated under 10 CFR Part 76 of the Commission's
regulations. The NRC staff has developed Office of Nuclear
Material Safety and Safeguards (NMSS) Policy and Procedures
Letter 1-53 to implement the "Backfitting" provision of 10
CFR 76.76. This procedure is available for inspection at the NRC
Public Document Room and Local Public Document Rooms discussed
below.

DATES: The NMSS Policy and Procedures Letter 1-53 is effective on March 3, 1997 as an interim procedure. Comments on the may 21, 1997 interim procedure are due on or before (insert date 60 days after the date of publication in the Federal Register).

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. ATTN: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland 20852, between 7:45 am and 4:15 pm during Federal workdays.

Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street N.W. (Lower Level), Washington, DC and at the Local Public Document Rooms (LPDRs), under Docket No. 70-7001, at the Paducah Public Library, 555 Washington Street, Paducah, Kentucky 42003; and under Docket No. 70-7002, at the Portsmouth Public Library, 1220 Gallia Street, Portsmouth, Ohio 45662.

Copies of NMSS Policy and Procedures Letter 1-53 may be obtained as indicated in the Discussion portion of Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Tom Wenck, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-8088.

SUPPLEMENTARY INFORMATION:

Discussion

On November 26, 1996, the Director, NMSS, issued the initial Certificates of Compliance to the United States Enrichment

Corporation, authorizing the continuing operation of its GDPs.

When the certificates became effective on March 3, 1997, the U.S.

Nuclear Regulatory Commission (NRC) assumed regulatory

jurisdiction over the GDPs from the Department of Energy.

Section 76.76 of Part 76 to Chapter I of Title 10 of the <u>Code of Federal Regulations</u> (CFR) contains a provision on "Backfitting."

"Backfitting" is defined in 10 CFR 76.76 to be "... the modification of, or addition to, systems, structures, or components of a plant or to the procedures or organization required to operate a plant; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules, that is either new or different from a previous NRC staff position." The intent of 10 CFR 76.76 is to provide a process by which to manage staff's imposition of new plant-specific and/or generic regulatory staff positions on the GDPs.

Although backfits are expected to occur and are a part of the regulatory process, it is important for sound and effective regulation that backfits are conducted in a controlled process. The NRC staff has developed NMSS Policy and Procedures Letter 1-53 on GDP generic and plant-specific backfitting. Copies of this procedure can be obtained from the Commission Public Document Room (PDR), 2120 L Street, N.W., Washington, DC and at the Local Public Document Rooms (LPDRs), under Docket No. 70-

7001, at the Paducah Public Library, 555 Washington Street, Paducah, Kentucky 42003; and under Docket No. 70-7002, at the Portsmouth Public Library, 1220 Gallia Street, Portsmouth, Ohio 45662.

Appendix 1 to NMSS Policy and Procedures Letter 1-53 provides guidance to the NRC staff on the proper NRC mechanisms (e.g., rulemaking) to use in establishing or communicating legal requirements and NRC staff positions to certificatees. Appendix 4 contains guidance to the NRC staff for making backfit determinations. Once a backfit determination has been made, and the proposed backfit does not meet either of the 2 exceptions¹ given in 10 CFR 76.76(a)(4)(i) and (ii), the NRC staff is required by 10 CFR 76.76(a)(3) to perform a cost/benefit analysis to determine "that there is a substantial increase (emphasis added) in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that plant are justified in view of this increased protection."

These exceptions are backfits that are necessary in order to ensure (a) that the plants provide adequate protection to the health and safety of the public and are in accord with the common defense and security, or (b) to bring the plants into compliance with the certificates, rules or orders of the Commission, or into conformance with written commitments by the Corporation.

Appendix 3 of NMSS Policy and Procedures Letter 1-53 contains guidance on application of the "Substantial Increase" Standard. This standard provides qualitative criteria for NRC staff to make a safety/safeguards "net benefits" determination of cost/benefits for the proposed backfit where a quantitative approach is not feasible.

NMSS Policy and Procedures Letter 1-53 is the first backfit procedure developed for facilities other than nuclear power reactor facilities. In addition, the GDPs are existing facilities which have operated under the Department of Energy for a number of years. Recognizing that this procedure may be addressing new issues, the NRC will accept public comments which focus on specific technical contents of the procedure.

Opportunity for Comments

The GDP backfit implementing procedure will be used by the NRC staff as an interim procedure pending completion of public review and resolution of comments on this <u>FR</u> Notice. Comments will be accepted which focus on the specific appendices discussed above. Comments in other areas of the procedures will be considered if they are directly related to the backfit issue. Procedures

such as NMSS Policy and Procedures Letters are used by NRC as guidance to the NRC staff on NRC's internal management process.

Dated at Rockville, Maryland this /// day of Maryland 1997.

For the Nuclear Regulatory Commission.

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John T. Greeves, Acting Director Office of Nuclear Material Safety and Safeguards