POLICY ISSUE
(Notation Vote)

June 1, 2005 SECY-05-0097

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: OPTIONS FOR PERMITTING VISITORS OF HOSPITALIZED PATIENTS TO RECEIVE DOSES IN EXCESS OF CURRENTLY PERMITTED LEVELS

PURPOSE:

The purpose of this paper is to obtain Commission approval of the staff's recommended course of action (Option 3).

SUMMARY:

The Commission, in Staff Requirements Memorandum (SRM)-SECY-04-0107, directed the staff to consider methods, and to recommend a course of action, to quickly and efficiently permit some visitors in exceptional cases to receive doses above current regulatory limits if warranted by the patient's needs. Options for setting and controlling doses to hospital visitors are examined, and an approach that is designed to provide appropriate controls is proposed. The paper considers possible dose limits that differ from the current regulatory limits for such situations, examines appropriate control measures to ensure the safety of the visitors, and discusses methods that may be used to implement the suggested approach. The staff recommends that the licensee, subject to appropriate controls and pre-established guidelines,

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be permitted to propose a dose limit for the specific case under consideration at its facility. The Nuclear Regulatory Commission (NRC) regional office would issue the necessary exemption for the case, again using pre-established protocols to expedite this process.

BACKGROUND:

Members of the public visiting patients in the hospital who are undergoing nuclear medicine or brachytherapy procedures receive radiation doses as a result of radiation emanating from the patient. The actual dose received depends on many factors, such as the type of procedure the patient is undergoing, the frequency and duration of the visits, the proximity to the patient and, in some cases, the extent of involvement of the visitor in the patient's care and comfort. The licensee is responsible for minimizing these doses and for maintaining them within the levels specified in 10 CFR Part 20. The permissible annual dose to any member of the public, under 10 CFR 20.1301(c), including visitors, is normally restricted to 1 millisievert (mSv) [0.1 rem]. However, the regulations permit visitors to an individual who cannot be released under 10 CFR 35.75, to receive a dose of up to 5 mSv (0.5 rem) provided certain conditions are met.

Two recent cases involving exposure of visitors have shown that these limits are not sufficient to take certain unusual patient needs into account. Specifically, the care of the patient sometimes requires the active participation of a member of the public, such as a parent, offspring, or other family member or friend, who will be referred to in this paper as a caregiver, to distinguish such a person from the casual visitor. Such active participation in patient care sometimes cannot be accomplished while keeping the dose to the caregiver within the current 1 mSv (0.1 rem), or even the 5 mSv (0.5 rem), regulatory limit. The licensee in such cases will, on the one hand, be faced with potential enforcement action by the NRC if the doses are permitted to exceed the limits and, on the other hand, may compromise the patient's well-being and recovery if the limits are enforced. In some situations, the licensee cannot enforce the limits because the caregiver refuses to comply with instructions designed to minimize radiation dose.

The mechanism currently used to grant relief from such situations is to require licensees to request an emergency, case-specific, exemption to the license, to permit a higher dose limit for the particular case in question. In accordance with this mechanism, the NRC staff make the determination as to the dose that may be allowed. Although this approach does achieve the desired purpose, namely it permits licensees in special circumstances to exceed the 5 mSv (0.5 rem) regulatory limit, it suffers a number of shortcomings: (1) There are few pre-established procedures to ease and standardize the granting of such exemptions; (2) Because there are no pre-established requirements, the current approach may not ensure proper control of the caregiver's exposures; (3) The lack of Agency policy is likely to lead to a lack of consistency and uniformity in granting exemptions and in the control measures required by such exemptions; and (4) The current regulatory policy in this area implies that caregiver doses above 5 mSv (0.5 rem) are to be avoided and are to be permitted only in emergencies. (This, in fact, is not necessarily the case, and a cost-benefit analysis of many caregiver situations would most likely indicate that exceeding the 5 mSv (0.5 rem) limit for a caregiver, even by a large margin, often yields a net benefit and should be supported.) This paper proposes methods to improve the current approach by making it more efficient and uniform in its implementation, as well as providing the licensee with the opportunity to more closely tailor the caregiver dose limit to the case under consideration.

DISCUSSION:

For clarity of presentation, the discussion of the issues is divided into three independent areas for consideration: (1) selection of a dose limit for the caregiver; (2) controls on exposure to be implemented by the licensee; and (3) regulatory mechanisms for implementing the limit and controls.

In the following discussion, an unqualified reference to dose should be understood to mean effective dose to the exposed person.

1. Dose Limits to Caregivers:

A number of possible dose limits have been proposed for the caregiver exposure situation. Many of these proposals use the annual occupational dose limit as a reference and appropriate limit. For example, the National Council on Radiation Protection and Measurements (NCRP) recommends a limit of 50 mSv (5 rem), annually, for the caregiver [NCRP Commentary No. 11, 1995], which is numerically equal to the annual occupational dose limit NCRP recommends for implementation in the US. The International Commission on Radiological Protection (ICRP), in its draft 2005 recommendations, suggests a limit of 20 mSv (2 rem) in a year [2005 Recommendations of the International Commission on Radiological Protection, Draft for Consultation, 2004], which is the annual occupational dose limit it recommends for worldwide implementation. Because NRC's occupational dose limit in 10 CFR 20.1201(a) is 50 mSv/yr (5 rem/yr), the appropriate caregiver dose, if based on this approach, would be 50 mSv (5 rem).

Another possible basis for selection of caregiver dose could be derived from the guidelines and limits used for emergency situations. Such situations normally involve a one-time acute exposure, much as is the case with the caregiver situation. NRC's 10 CFR 20.1206(e)(1) permits Planned Special Exposures (PSEs), for occupationally exposed workers, of up to 50 mSv (5 rem) in a year, in addition to the routine annual limit of 50 mSv (5 rem). Furthermore, the lifetime dose that may delivered under the PSE provision is 250 mSv (25 rem), again, in addition to the routine annual dose of 50 mSv (5 rem), as specified in 10 CFR 20.1206(e)(2).

As an alternative, the staff has considered the possibility of not imposing any dose limit on caregivers by regulation, but regarding their exposures as being made necessary by, and hence as being part of, the patient's medical treatment. This option would permit the licensee to set the appropriate limit on a case-by-case basis, subject to appropriate regulatory controls, and as the details of the case dictate. Under this approach, the need for exposure of a caregiver above applicable limits would be more appropriately determined by the patient's treating physician, probably in collaboration with the caregiver and the radiation protection staff, on a case-by-case basis. The licensee's radiation safety committee, if one is present, may help in setting policy in this area and in monitoring its general implementation. Furthermore, the dose level that the caregiver may be permitted to receive would also be determined by the physician and the radiation protection staff depending on the requirements of the particular case on hand. The licensee would then request a license exemption to be issued by the NRC regional office. After evaluation of the merits of the case and the suitability of the requested dose limit, the regional office would quickly issue the requested exemption. Appropriate controls on radiation exposures to the caregiver would be implemented. These controls are discussed in the next section. Provisions would also be in place to allow modification of the dose limit initially selected by the licensee if the patient's condition changes significantly,

making it necessary to modify treatment approaches or to change the level of care and support required to be provided by the caregiver.

As an integral part of this approach, the guidance to be provided to the Regions, Agreement States, and licensees will recommend a default dose limit of about 20 mSv (2 rem) as a starting point for this process. Experience has demonstrated that most cases can be accommodated within this limit. The guidance will also advise that licensees may request a higher limit if they believe that to be necessary, and the Regions will be authorized to approve the requested limit if, after discussions with the licensee, if the staff believes that it is appropriate to do so. The guidance will also provide for an upper bound to the dose limit that may be requested by the licensee, such as 50 mSv (5 rem). Cases requiring dose limits above 50 mSv (5 rem) would be referred to NMSS for special consideration.

2. Controls on Exposures:

Once a decision is made to permit a caregiver to be exposed to doses above the current regulatory limit of 5 mSv (0.5 rem) [10 CFR 20.1301(c)(1)], appropriate controls would be called for and would have to be implemented by the licensee. These controls would be required as one of the conditions for granting the necessary exemption to exceed the applicable regulatory limit. The controls recommended by the staff would include the following:

a. Before the start of caregiver exposures, the licensee would issue a written authorization for such an exposure, signed by a designated person such as the treating physician, the authorized user, or the radiation safety officer. The authorization would identify the caregiver, provide a justification for the exposure, specify the estimated exposure dates, and specify the authorized dose. If it were to become necessary to change the chosen limit as a result of a significant change in the patient's medical condition, the exposure authorization would be amended and signed by the same authorized person or persons. A clear justification for such a change in limit must be documented.

b. After approval of the caregiver exposure and dose limit by NRC, the caregiver must be instructed on the risks of radiation exposure and provided training on radiation control and the methods that may be used to keep radiation exposures as low as is reasonably achievable (ALARA). A form signed by the caregiver will indicate that the caregiver has been instructed, has understood the instructions, and has accepted any risks that may accompany the radiation exposures. The instructions to the caregiver could be based on a pre-prepared guide that details the various risks of radiation exposure, including cancer risks as well as deterministic risks, especially if a potential or actual pregnancy is involved. This guidance could be prepared by NRC along the same lines as Regulatory Guide 8.13 [Instruction Concerning Prenatal Radiation Exposure] and Regulatory Guide 8.29 [Instruction Concerning Risks from Occupational Radiation Exposure], but tailored to the caregiver situation.

c. Exposure of minors as caregivers would be subject to careful evaluation by the licensee's medical staff to ensure that sufficient justification exists for the exposures, and that the minor's developmental stage is taken into account in these evaluations. This would be consistent with 10 CFR 20.1207, which limits

occupational dose to minors to 10 percent of that for adult workers. Parental consent may also be required in such cases. Actual or potential pregnancies would be handled in the same manner, by the hospital's medical staff, as in cases involving pregnant women or women of childbearing age who are to undergo diagnostic or therapeutic procedures involving radiation exposure. This procedure would involve questions on the possible pregnancy of the caregiver and advice on the risks of radiation exposures to the embryo/fetus.

d. The caregiver would be provided with personnel monitoring devices that permit real-time monitoring of the dose received. Such devices may be the traditional pocket ionization chambers, or some of the more sophisticated alarming dosimeters or electronic dosimetry. Whatever the device selected, it must be calibrated, reliable, and easy to read. The caregiver could also be provided with a backup device, such as a film badge or thermoluminescence dosimeter (TLD), to be processed by an accredited processor as required by 10 CFR 20.1501(c).

e. The caregiver's dose would be recorded at specified intervals and the running total to date periodically monitored and approved by the responsible radiation protection supervisor.

f. The hospital staff should attempt to implement any ALARA measures that are consistent with the caregiver's care-giving functions. Examples of such measures may include: (1) instructing the caregiver to sit at some distance from the bed when a closer approach is not required; (2) leaving the room when the patient is resting or does not need assistance; (3) remaining behind shields if appropriate; and (4) staying on the side of the patient where the radiation field is lowest. In addition, and where feasible, the care-giving functions may be divided among several persons, such as, for example, both parents of a child, or several adult children caring for a parent.

3. Regulatory Mechanisms for Implementing the Limit and Controls:

The options for selecting possible dose limits for the caregiver, and the advantages and disadvantage of each, are discussed in this section.

Option 1 - Base the caregiver dose limit on the annual occupational dose limit.

This option would impose a dose limit of 50 mSv (5 rem) on the caregiver.

Advantages:

- A caregiver dose limit equal to the annual occupational limit has already been proposed by both the NCRP and the ICRP. Therefore, adoption of such a limit would require minimal justification.
- The annual occupational dose limit has long been in use, and has gained conceptual acceptance as a reasonable operating parameter. It would, therefore, be relatively easy to transfer the concept to the caregiver situation.

- A limit of 50 mSv (5 rem) is likely to accommodate most, although not all, caregiver situations.

Disadvantages:

- Establishing a formal dose limit would involve rulemaking. However, in view of the relatively small number of cases that would be affected, rulemaking would not be justified.

- NCRP expressed its caregiver limit as an annual limit. However, the caregiver situation is not an annual occurrence, but rather a one-time situation, or at least one that is very infrequently repeated. It is unclear how the risks implicit in an annual dose limit may be meaningfully transferred to a one-time exposure.

- A limit of 50 mSv (5 rem) would likely accommodate most caregiver situations. However, as a recent experience has indicated, certain treatment modalities may require higher caregiver limits. Such cases would then require case-by-case exemptions.

- Using the annual occupational limit as a reference for a very infrequent exposure situation may be unjustified. The cost-benefit considerations that are typically used to select annual dose limits, whether occupational or public, do not apply to the caregiver situation, and it may be inappropriate to use the dose limits derived using one set of cost-benefit considerations, to a situation controlled by a very different set of considerations.

Option 2 - Base the caregiver dose limit on 250 mSv (25 rem) PSE lifetime limit.

This option would set the dose limit for the caregiver at 250 mSv (25 rem).

Advantages:

- There is a stronger conceptual justification for this limit than there is in adopting the annual occupational dose limit. Both the caregiver situation, as well as that to which the PSE applies, are very unusual, often once-in-a-lifetime situations, for any specific individual.

- The limit is probably high enough to accommodate all caregiver situations.

Disadvantages:

- As is the case with Option 1, establishing a formal limit would involve rulemaking, which is not justified in view of the small number of cases that would be affected.

- As with any other limit, setting a 250 mSv (25 rem) limit may weaken the incentive to justify both the need for caregiver exposures, as well as the need to minimize the dose. A limit gives the impression that the dose is “available” to be used when needed. This may result in caregivers receiving higher doses than would be the case if the licensee justified the exposures and set the limits for the specific cases.

- Setting a limit implies a cost-benefit equation established by regulators, who may not share the caregiver's value system and the caregiver's system of judging the risks and benefits. Stated differently, a preset regulatory limit imposes the regulator's value system on the caregiver's decisions relating to caring for the patient and the levels of risk deemed by the caregiver to be acceptable under the circumstances. In a situation as personal and as critical as that of caring for a seriously ill patient, such imposition of a risk-benefit system by outsiders may be unwarranted and should be avoided. This disadvantage is also shared by Option 1 above.

- Although ALARA is a requirement in all cases, many potential ALARA measures will be overridden by the needs and logic of the specific case. They will, necessarily, assume a secondary role after the needs of the patient have been adequately met, in the opinion of the medical staff as well as that of the caregiver. It is, therefore, likely that the caregiver exposures will not, in many cases, be much constrained by ALARA, but rather by the limit. A limit set by the licensee for the specific case may likely be much lower, and to more successfully constrain the exposures, than one set by regulation and that is sufficiently high to accommodate all, or most, caregiver situations.

Option 3 - Allow the licensee to establish the limit on a case-by-case basis.

This option, subject to appropriate regulatory controls, would leave the responsibility of justifying a caregiver exposure, and of estimating the needed case-specific dose limit, to the licensee. The NRC staff would develop uniform procedures to facilitate approval of licensee-established limits. The default dose limit for this approach would be set at about 20 mSv (2 rem), and this is expected to be adequate for most cases. The NRC would also not approve licensee-proposed dose limits that are considered excessively high, such as any limit above 50 mSv (5 rem), without special justification by the licensee and assessment by NMSS staff.

Advantages:

- This approach permits a case-by-case determination of the dose likely to be required to accommodate the caregiver's functions. The need for the exposure, as well as the selected dose limit, will have to be justified in each case. This could lead to licensee-assigned limits that are significantly lower than limits established by regulation and designed to accommodate all, or nearly all, caregiver situations. It may also lead to fewer people being exposed as caregivers than would be the case if a limit is established by regulation. This is likely to be the case because the exposure of each caregiver, as well as the level of such exposures, will have to be carefully justified by the licensee, and would then become the subject of a specific exemption issued by the NRC, either for each caregiver or for the license. The existence of a pre-established limit would lower the threshold for justification of exposures, and would remove the need to justify the level of the exposure.

- This approach permits the caregivers, in consultation with the medical and radiological staff, to make decisions based on their own value systems regarding what is important and what risks are justified.

- This approach is likely to lead to lower doses to caregivers than would be the case if a sufficiently high regulatory limit applicable to all cases were imposed.

- Procedures for monitoring and controlling caregiver exposures would be just as stringent as those that would be in place with a regulatory limit, and would be just as effective.

- This option does not involve rulemaking.

Disadvantages:

- The main disadvantage of this approach is that it is novel, and may be viewed with some misgiving by both some regulators, some licensees, and possibly some members of the public. However, it does not, in fact, differ significantly from the current approach, but only formalizes and streamlines the procedures for requesting and granting exemptions and controlling exposures, and provides more flexibility to the licensees and the NRC regions in setting appropriate limits.

- Different licensees are likely to set different case-specific limits for similar caregiver situations, and so there would likely not be consistency in exposure levels. Note, however, that this would also be the case even if regulatory limits for caregivers were established, because the actual doses incurred within such a limit would still vary from licensee to licensee, depending on the details of the situation and the licensee's success in minimizing the dose.

4. STAFF RECOMMENDATIONS:

After considering the various options available to permit caregivers to be exposed to doses above the current regulatory limit, the staff recommends Option 3. The proposed actions to implement this option are outlined below.

a. Permit licensees to justify exposing caregivers to doses above current regulatory limits, and permit licensees to set the appropriate limit on a case-by-case basis. The exposures would be authorized by NRC on a case-by-case basis, by granting an appropriate exemption for the case in question. These authorizations would be granted promptly, as requested by the licensee. Such authorizations would also activate the required controls, as described in Section 2, above. This approach differs from current practice in that the licensee will select the desired limit, there will be pre-established procedures for approving the requests expeditiously, and there would also be pre-established requirements and controls to be implemented by the licensee upon approval of the request. A default limit of 20 mSv (2 rem) would be used, and requests for limits above 50 mSv (5 rem) would be referred to NMSS for special consideration.

b. Develop the procedures, guidance and training documents, and approval protocols to facilitate rapid approval of license amendments, when requested by licensees. These documents would serve as bases for implementing the program by the NRC Regional Offices and would also serve as guidance for Agreement State programs when designing and implementing their corresponding programs.

c. Issue a Regulatory Issue Summary (RIS) informing licensees of the program, of the procedures to be followed for obtaining prompt approval of their request, and of the controls to be implemented after approval of the request. The RIS would also provide guidance on approaches that licensees may use in setting appropriate limits in each case. .

d. Develop the details of the regulatory mechanisms to be used to implement the selected option. These details, which include enforcement, notifications, and reporting, have not been developed in this paper. They would be established after Commission direction on the approach to be taken by the staff has been conveyed.

Discussions were held with NRC staff in different NRC Offices and the Regions, with members of the Advisory Committee on the Medical Use of Isotopes (ACMUI), and with the Agreement States. These discussions have shown that there is consistent support for staff's preferred option, and have provided comments and suggestions, conveyed orally and by electronic mail to the NRC staff, that have been incorporated to improve the proposals presented in this paper.

A review of the comments received from the ACMUI and the Agreement States indicated that they are overwhelmingly in favor of case-by-case implementation of the staff's preferred option, without corresponding rulemaking. The staff agrees with this position and believes that case-by-case implementation, via, license amendments, supported by the appropriate quick-approval mechanisms and guidance documents, as well as inspection and other NRC oversight, would result in a successful program that would safely and efficiently accomplish the intended goals. Experience with this graded approach, after a sufficient number of cases have been implemented, may suggest the need for modifications or adjustments. It is expected that the number of cases that would be subject to this program will be sufficiently small to be efficiently addressed using license amendments rather than rulemaking. However, should the number of cases become sufficiently large, this approach will be re-evaluated and the possibility of rulemaking will be considered.

RESOURCE REQUIREMENTS:

The option recommended by the staff is not expected to require significant resources to implement because much of the program can be implemented within current programs. Some minimal resources will be needed to develop appropriate guidance for the Regional Offices and Agreement States to ensure uniformity of program implementation. A generic communication will also be required to inform licensees of the availability of this program and its constraints. It is expected that the guidance documents will require about 0.2 FTE to complete over a period of about 12 months. Subject to Commission approval of the proposed actions, it is anticipated that the work would be performed during fiscal years 2005 and 2006, and should be completed by mid-2006. No currently planned work will be affected. The Commission will be informed of completion of the proposed work and the start of its implementation.

The information on resources and schedule reflect the current environment. If a significant amount of time (greater than 30 days) passes or the Commission provides the staff direction that differs from, or adds to, the staff's recommended actions, this section of the paper would need to be revisited after issuance of the draft SRM.

COORDINATION

The Office of the General Counsel has reviewed this paper and has no legal objection.

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