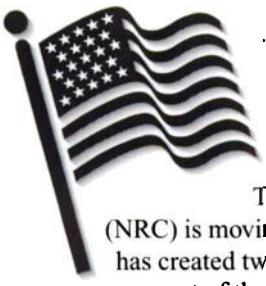

NRC Reform Effort Underway

The Nuclear Regulatory Commission (NRC) is moving forward with reform efforts and has created two groups that will guide the development of the new regulations. A steering group composed of management-level staff will provide direction, and a working group made up of NRC and agreement-state staff will present alternatives to the current regulations for the steering group to consider.

The working group met August 19-21, 1997, to discuss regulatory alternatives to certain areas of Part 35. The general structure of Part 35 will likely have areas of regulation that apply to all modalities and then specific areas that apply only to certain modalities. Each modality will have a section. The two modalities currently identified for nuclear medicine are low-dose unsealed diagnostic and high-dose unsealed therapeutic sources. The working group also identified the following areas for further discussion: quality management (QM) program requirements, radiation safety committee requirements, training and experience requirements, patient notification requirements and recordkeeping format requirements. The working group was charged with developing regulatory alternatives to present to the steering committee for further decision making.

Quality Management Program

The working group developed three options for regulatory alternatives:

1. Modality-specific regulations, with only brief general language that would apply to all modalities
2. Broader general language with specific exemptions for modalities for which QM is unnecessary
3. Status quo

Radiation Safety Committee

The main focus of this discussion was on modalities requiring a radiation safety committee and, if necessary, what the components would be. Options ranged from requiring quorums and identifying specific members to no quorum or membership requirements. It was generally agreed that unsealed and sealed diagnostic sources would not require a radiation safety committee.

Patient Notification

The issue of patient notification was one of great contention, with the working group split on the issue of whether the NRC should notify anyone that a physician has made a potentially harmful error in treating a patient.

The options proposed included the following:

1. Maintain status quo.
2. Notify the NRC only.
3. Notify the NRC and referring physician.
4. Notify the NRC, referring physician and patient/guardian (no exemptions).
5. Notify the NRC, referring physician and patient/guardian (only if detrimental effect).

Training and Experience

There was a significant amount of discussion of this topic as the working group examined the issue of training and experience for the authorized user, the radiation safety officer, the authorized nuclear pharmacist and ancillary personnel such as technologists.

During the meeting, the group focused on the training and experience of the authorized user and developed the following options:

1. Status quo
2. Board certification or hours of experience (modified), focusing on radiation safety
3. Option 2 plus the requirement of an exam to prove knowledge (administered either by the NRC or a third party)
4. Licensed physician
5. Licensed physician plus exam (no specific hours identified)
6. Licensed physician plus exam plus specific hours of clinical and classroom experience

For nuclear medicine, the working group felt that options 1-6 were viable for low-dose unsealed diagnostic sources and that only option 4 did not apply to high-dose unsealed diagnostic sources.

The working group is completing its comments on each of these sections and preparing a document that will be forwarded to the steering committee for review. That document will outline the pros and cons of each of the alternatives and will be completed in advance of two public workshops to be held October 28-30, 1997, and November 12-14, 1997.

Ward Valley Update

Prior to the start of the August 1997 recess, the Senate Energy and Natural Resources Committee heard testimony on the transfer of federal land to the state of California. Although many committee members support the proposal, there were several present who voiced opposition. Prominent among the detractors were Senator Barbara Boxer (D-CA), Representative George Miller (D-CA), and Representative Bob Filner (D-CA). Representative Brian Bilbray (R-CA) was the only member from California to offer positive testimony. Other supporters included Senator Frank Murkowski (R-AK), sponsor of S. 964, and Senator Jon Kyl (R-AZ).

The purpose of the hearing was to decide if Congress should intercede on behalf of California and pass S. 964, legislation authorizing the sale of Ward Valley to the state. California has been waiting for the Department of the Interior to proceed with this matter for over four years.

John Garamendi, spokesperson for the Department of the Interior, insisted that the main reason this land purchase has not moved

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Mathew L. Thakur, PhD

Eighth Congress of the International Society of Radiolabeled Blood Elements

The Eighth Congress of the International Society of Radiolabeled Blood Elements (ISORBE) was held May 24-27, 1997, in Castel Gandolfo near Rome, Italy. The symposium was attended by 138 participants from 27 countries. A total of 103 abstracts were presented, of which 14 were invited, and the remaining 89 were chosen by an international panel of reviewers from 105 abstracts submitted. Scientific program abstracts were published in *Nuclear Medicine Communications* (*Nucl Med Commun* 1997;18:457-495).

Novel clinical and experimental investigations with applications of radiolabeled platelets, separated lymphocytes and monocytes and mixed population of white blood cells continue. There is an increasing trend toward using ^{99m}Tc as a tracer, although ^{111}In-labeled blood cells continue to serve as the standard in both routine and experimental applications. The major thrust of research presented regarding the development of new radiopharmaceuticals was in the preparation and evaluation of receptor-specific biomolecules that will selectively label neutrophils in vivo. These agents include monoclonal antibodies, intact or fragments thereof, peptides and a variety of cytokines.

Quality and originality of science were judged by a panel of reviewers, who identified four outstanding presentations by young investigators for the following awards:

- Amersham Health Care Award: C. van der Laken, PhD (Nijmegen, The Netherlands), Infection imaging with interleukin-1, its receptor antigonist and a chemotactic peptide: A study of two animal models.
- DuPont Award: E. Pracaccini, MD (Rome, Italy), ^{99m}Tc-IL-2 scintigraphy in patients with thyroid disease.
- Byk Gulden Italia Award: F. Jamar, MD (Brussels, Belgium), Imaging endothelial activation using ^{99m}Tc anti-E selectin Fab in rheumatoid arthritis.
- Byk Gulden Italia Award: S. Gratz, MD (Gottingen, Germany), Intraindividual comparison of ^{99m}Tc-labeled anti-SSEA-1 antigranulocyte antibody and ^{99m}Tc white blood cells for imaging infection.

The Ninth ISORBE Congress will be held in 1999 in Rio de Janeiro, Brazil.

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Government Relations

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forward lies with California. Garamendi claimed that the state had established numerous roadblocks throughout the process, effectively stalling the transfer. As evidence of this, the Department noted that the state of California had refused at every occasion to participate in joint testing. Ultimately, the Department claims that moving forward with this sale would be hasty, citing the need for further unbiased testing on issues that have arisen since the original Environmental Impact Statement (EIS) and National Academy of Sciences (NAS) reports were completed.

California has agreed to do additional testing but claims that it is prevented from doing so by the Bureau of Land Management, which is withholding a permit allowing access to the area. At this point, Chairman Murkowski noted a memo in which the Department of the Interior asked the Bureau of Land Management to do everything it could to encourage joint testing.

The spokesperson for California said that no new, relevant information has been brought forth to merit an additional Significant Impact Statement (SIS). Further, the state sees the Department of the Interior's demand for joint testing as additional evidence of that agency's wish to control the facility. The state also pointed to oversight rules by the Department once transfer is complete and the Department's recommendation of appropriate alternate sites for consideration in future testing.

Those opposing the land transfer addressed several issues. Of primary concern were tritium levels at the facility and leaking at the Beatty site in Nevada. Additionally, many were concerned that radioactive waste at Ward Valley would be absorbed into the Colorado River, which supplies drinking water to the neighboring area. Members of area Native American tribes have raised claims that they were excluded from the original EIS and NAS reports.

Noting that the NAS report mentioned the leaking at the Beatty site but ruled it out as a significant factor, proponents claimed that Beatty is not a reliable indicator of Ward Valley's success. They also reported that tritium levels will be lower than were originally indicated in the NAS report and that absorption of radioactive waste into the Colorado River drinking water supply has been found to be highly unlikely. Representative Bilbray pointed out in his testimony that the General Accounting Office found that the Ward Valley facility would not adversely affect Native Americans' cultural sites.

The hearing ended with the spokespersons for the state of California and the Department of the Interior agreeing to meet and discuss the stalemate. Senator Murkowski encouraged this, hoping that they would come to an agreement without the assistance of Congress.