Feature Article

Emergence of a New Bioengineering Infrastructure and a "College of Clinical Engineering"

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A growing number of bioengineers favor the creation of a new infrastructure to represent their interests. Clinical and biomedical engineers may soon enhance their national recognition with a Clinical Engineering College.

The **Alliance for Engineering in Medicine and Biology** (AEMB) and the **U.S. National Committee on Biomechanics** (USNCB) sponsored the first of three workshops in August, 1989, "to determine those elements necessary in a structure which could represent bioengineering and address those problems which are common to the field at large." The workshop cochairmen were **Arthur T. Johnson**, Ph.D., and **Robert M. Nerem**, Ph.D. A *Task Force on Clinical Engineering* was formed in May, 1989, to pursue a similar course of action specifically for clinical and biomedical engineers. **Yadin David**, Ph.D., was elected chairman. He represented Task Force interests at the AEMB-USNCB workshop. This article reports on the general topics discussed and the directions that the respective groups appear to be taking. Developments arising within and between the two groups are also examined.

INTRODUCTION

Establishing an *identity* has been one of the goals of clinical engineering for more than 20 years. The needs of this profession are broader than just identity, however. They extend to *recognition*, *visibility*, and *influence* as well. The goals, as with any professional group, include identification of the profession, recognition of the field and the individuals active in it, visibility for the contributions of bioengineers, and influence both in shaping public opinion and national policy. Biomedical and clinical engineers are accelerating their search for professional identification. Clinical engineering has been called "an enigma in healthcare" while biomedical engineers are said to be "like a rare gas: widely dispersed and not easily identified." Clinical engineers conducted an Open Forum last May during the St. Louis **Association for the Advancement of Medical Instrumentation** (AAMI) meeting to determine whether or not a new society might solve their collective dilemma. While the immediate formation of a new organization was defeated, an *Ad Hoc Task Force on Clinical Engineering* was formed to explore dozens of issues. The larger body of **bioengineers** is exper-

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iencing similar crises. Readers should review *The Profession of Clinical Engineering* and *What Do Clinical Engineers Want from Professional Societies?* (Goodman, 1989 and McBride, 1989), as well as *An Open Forum On: A National Clinical Engineering Society* (Pacela, 1989) and *The Future of Clinical Engineering in the 1990s* (Newhouse, 1989) to understand the background of these precedent-setting events and to appreciate their significance.

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What is an Engineer?

Developing an identity and achieving recognition are dependent on definitions of terms; first, what is an engineer? The **National Research Council**'s *Committee on the Education and Utilization of the Engineer* (CEUE—National Research Council, 1988) recommends an interesting series of operational definitions that could be used by all involved:

"*Engineering*: Business, government, academic or individual efforts in which knowledge of mathematical, physical and/or natural sciences is employed in research, development, design, manufacturing, systems engineering, or technical operations with the objective of creating and/or delivering systems, products, processes, and/or services of a technical nature and content intended for use.

"*Engineering Community*: People meeting at least one of the following conditions:

- Actively engaged in engineering, as defined above;
- Actively engaged in engineering education;
- Qualified as an engineer, engineering technologist, or engineering technician, as defined below, and actively engaged in such engineering support functions as engineering management or administration, technical sales, or technical product purchasing;
- Qualified as an engineer, engineering technologist, or engineering technician, as defined below, who was but is not now actively engaged in engineering, engineering education, or engineering support.

"*Engineer*: A person having at least one of the following qualifications:

- College/university B.S. or advanced degree in an accredited engineering program;
- Membership in a recognized engineering society at a professional level;
- Registered or licensed as an engineer by a governmental agency;
- Current or recent employment in a job classification requiring engineering work at a professional level.

"*Engineering Technologist*: A person having at least one of the following qualifications:

- A bachelor's degree from an accredited program in engineering technology;
- Current or recent employment in engineering work, but lacking the qualifications of an engineer as defined above.

"*Engineering Technician*: A person having at least one of the following qualifications:

- A degree or certificate from a one- to three-year accredited technical program;
- Current or recent employment in engineering work, but lacking the qualifications of an engineer as defined above and at a lower job level than that of an engineering technologist." (National Research Council, 1988)

The CEUE definition is certainly broad enough to include clinical and biomedical engineering. However, it is not universally accepted in this field. It also establishes distinctions between technicians and technologists that are not in broad use in biomedical and clinical engineering. AAMI defines a clinical engineer as:

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"A professional who brings to healthcare facilities a level of education, experience and accomplishment which will enable him to responsibly, effectively, and safely manage and interface with medical devices, instruments, and systems, and the user thereof during patient care; and who can, because of this level of competence, responsibly and directly serve the patient, and interact with physicians, nurses and other healthcare professionals relative to their use and other contact with medical instrumentation and systems." (Goodman, 1989)

Goodman and others opt for the more simple definition. They note that clinical engineering was created "by a dramatic increase in the use of electronic devices for patient care" (Goodman, 1989). Hence, clinical engineering represents "the application of engineering principles and skills in healthcare."

Definitional issues are further muddied when applied in terms of "degreed" professionals as opposed to those who are "certified" and "licensed." **Donald Strong**, staff associate for the **American Society for Engineering Education** (ASEE), explains that the *Engineering Manpower Commission* only collects data on bioengineers. He claims that only 12 accredited university/college programs offer baccalaureate, master's and doctoral degrees in biomedical engineering and that there are five others

which grant degrees in the broader field of bioengineering. "Even then," Strong says, "some schools award only B.S. degrees while others grant Ph.D.s and M.S.s." The new Quest Publishing *Bioengineering Education Directory*, however, lists at least 40 U.S. schools that grant biomedical engineering degrees at one or more levels (Pacela, 1989). The directory lists 13 others that grant degrees in bioengineering. Other schools have programs in biological, chemical, electrical and agricultural engineering with emphasis or minors in bioengineering.

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How Many Engineers Are There?

Attempts to determine the actual number of engineers in the United States only emphasize the broad dispersion and the difficulty of identifying clinical and biomedical engineers. Several recent reports predict a general enrollment fall-off in engineering and natural sciences. The **National Science Foundation**'s (NSF) *Directorate for Scientific, Technological and International Affairs* projects a shortfall of approximately 675,000 bachelor's degrees in the natural sciences and engineering by 2006 when compared to constant production at the 1984-86 average (National Science Foundation, 1989). While a "shortfall" will not become a true "shortage" unless the demand for skills exceeds the available supply of professionals, even the NSF's best estimates predict a national shortfall of 440,000. The agency indicates that the country could be "short" as many as 103,000 natural science and engineering Ph.D.s by the year 2006.

Where does that leave clinical and biomedical engineers? A soon-to-be-released report by ASEE is somewhat encouraging. The 1989 report of the *Engineering Manpower Commission* on bioengineering degrees granted states that 677 B.S.s were awarded this year, up from 636 in 1989.

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The number of master's degrees rose from 257 to 303, and 86 doctorates were awarded, compared to 70 the previous year. The grand total: 1,066 bioengineering degrees. Figures from the **American Association of Engineering Societies** were essentially identical.

Given the fact that many persons consider themselves clinical or biomedical engineers by virtue of their bachelor's or master's degrees, even though their subsequent degrees may be in other fields, one can sense the difficulty of establishing a group identity based on degree-granting schools, alumni and the like. It also underscores the difficulty of assessing "how many biomedical and clinical engineers" there are now and how many more will be needed in the future. The best-known clinical engineering professional societies, **IEEE/Engineering in Medicine and Biology Society** (IEEE/EMBS), AAMI, the **American Society for Hospital Engineering** (ASHE) and the **Biomedical Engineering Society** (BMES) estimate their combined membership at more than 15,000, but many professionals belong to two or three of these groups. Clinical engineers may represent less than a thousand of that number, according to some conservative estimates. The other society members include bioengineers, or biomedical engineering technicians (BMETs) of one kind or another. The AAMI membership includes M.D.s and other industry and medical professionals.

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THE ALLIANCE FOR ENGINEERING IN MEDICINE & BIOLOGY

While each of the key societies claims to meet the needs and represent the interests of its members, the need for an all-encompassing "umbrella organization" to accomplish loftier national-level goals was acknowledged in 1969 with the creation of the **Alliance for Engineering in Medicine and Biology** (AEMB). AEMB's 19 member associations believed the organization necessary to interpret and actively communicate issues in biomedical engineering "across the boundaries that separated medicine and the life sciences from engineering and the physical sciences" (AEMB, 1989). The members include: the

The groups were instructed to discuss policy and practical considerations relevant to the need for a "new infrastructure for bioengineering" and the creation/composition of a "new unifying organization."

American Association for Medical Systems and Informatics; the **American Association of Physicists in Medicine**; the **American College of Radiology**; the **American Institute of Chemical Engineers**; the **American Society for Artificial Internal Organs**; ASEE; ASHE; the **American Society for Testing and Materials**; the **American Society of Agricultural Engineers**; the **American Society of Civil Engineers**; the **American Society of Mechanical Engineers**; BMES; IEEE/EMBS; the **Instrument Society of America**; the **National Institute of Electromedical Information**; the **Neuroelectric Society**; the **Rehabilitation Engineering Society of North America** (RESNA—also known as the Association for the Advancement of Rehabilitation Technology); the

Society for Experimental Mechanics; and the **Society of Photo-Optical Instrumentation Engineers-International Society for Optical Engineering** (SPIE). AEMB is the U.S. affiliate to the **International Federation for Medical and Biological Engineering.**

"Turf wars" in recent years have impaired the Alliance, according to **Patricia Horner**, the organization's executive director. When the EMBS joined, for example, there was talk of certification in clinical and biomedical engineering. When the EMBS did not develop a formal program, AAMI—a charter AEMB member—created one on its own. Both groups asked the AEMB to arbitrate the dispute that followed. The net result, Horner says, was AAMI's withdrawal from the Alliance and the formation of two certification bodies. Although the certifying bodies ultimately united, there were other internal disagreements. The Alliance is "moribund" according to some, "all but dead" according to others.

One of the issues that surfaced during the AEMB's most turbulent internal struggle was the question of, "Who speaks for bioengineers?" The Alliance was substantially influenced, it was believed by some, by the IEEE/EMBS membership. Grassroots sentiments favored the creation of a new infrastructure. The Alliance and the USNCB obtained a grant from the **National Science Foundation** and a workshop was conducted in August, 1989, to "determine those elements necessary in a structure which could represent bioengineering and address those problems which are common to the field at large."

THE EMERGENCE OF A NEW INFRASTRUCTURE FOR BIOENGINEERING?

Approximately 55 persons, representing key societies and independent affiliates, attended the by-invitation event. The opening session featured "Bioengineering and Its Organization as a Community: Is There Need?" Workshop cochairmen Johnson and Nerem are past president of the AEMB and chairman of the USNCB, respectively. **Richard J. Gowen**, Ph.D., was keynote speaker the next morning. Gowen, who is past president of the **Institute of Electrical and Electronics Engineering** (IEEE), discussed "Issues Facing Bioengineering." Johnson chaired the session.

The first plenary session covered "Issues Facing Bioengineering: A Government Perspective." **Gilbert B. Devey**, B.S., technology consultant to the **American College of Radiology**, chaired the session. Speakers included **John C. Villforth**, Ph.D., director of the **Center for Devices and Radiological Health**; **Duane F. Bruley**, Ph.D., head of the NSF's bioengineering and environmental systems section; **Murray Eden**, Ph.D., chief of the bioengineering and instrumentation branch at the **National Institutes of Health**; and **Guy Hammer**, B.S., manager of the *Technology Transfer Program* of the **National Institute for Disability Rehabilitation and Research**. The day's luncheon topic was "Issues Facing Bioengineering: A Foundation Perspective." **Miles J. Gibbons, Jr.**, L.L.B., executive director of the **Whittaker Foundation**, delivered the keynote address.

The afternoon plenary session covered "Issues Facing Bioengineering: An Industry Perspective." The speakers were **Ronald B. Schilling**, Ph.D., senior vice president and general manager of **Toshiba America Medical Systems, Inc.**; **Alfred R. Potvin**, Ph.D., P.E., director of the *Medical Instrument System Research Division* at **Eli Lilly and Company**; and **Alan R. Kahn**, M.D., president of **Human Dimensions, Inc.** and vice president of research and development for **Criticare Systems, Inc**.

The third plenary, "Issues Facing Bioengineering: A University Perspective," was chaired by **Morton H. Friedman**, Ph.D., professor of biomedical and chemical engineering at **Ohio State University**. The speakers were **Theo C. Pilkington**, Ph.D., professor of biomedical and electrical engineering at **Duke University**; **Richard A. Foulds**, Ph.D., chairman of the Applied Sciences and Engineering department, *A.I. duPont Institute*, at the **University of Delaware**; and **Winfred M. Phillips**, D.Sc., dean of the **University of Florida** *College of Engineering*.

The final plenary addressed "Bioengineering and its Organization as a Community: The Organizational Issues." **Dov Jaron**, Ph.D., director of **Drexel University**'s *Biomedical Engineering and Science Institute*, was the organizer. Nerem and Johnson were the speakers.

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Meeting organizers divided the participants into five discipline- and interest-based working groups ahead of time. The groups were instructed to discuss policy and practical considerations relevant to the need for a "new infrastructure for bioengineering" and the creation/composition of a "new unifying organization." They were to report their ideas to the entire workshop.

IS THE ALLIANCE NO LONGER ADEQUATE?

The participants examined the existing umbrella societies, including the Alliance. Ironically, it was perceived as "successful, perhaps even too successful." Some group members said that the Alliance had not changed with the times, had neither a focus nor a financial base. Others stated a belief that the AEMB was "too closely tied to the *Annual Conference on Engineers in Medicine and Biology* (ACEMB)," a meeting that had lost the "cutting edge" in some respects. Moreover, the ACEMB resulted in competition between similar societies, according to some participants. The ACEMB was originally cosponsored by the Alliance and the IEEE; the last meeting occurred approximately two years ago, prior to IEEE's withdrawal from sponsorship. The **Biomedical Engineering Society** (BMES) was viewed as "too systems/physiology-

oriented;" the USNCB was compared to the AEMB—lacking a financial base. Furthermore, BMES and USNCB were said to suffer from a lack of identity caused, in part, by not having their own annual meetings.

A SURPRISING CONSENSUS

Both participants and attendees represented a broad cross-section of professions and organizations. As this article went to press, a *Workshop Steering Committee* was continuing to integrate the results into an action outline to be presented during the next workshop, scheduled for March, 1990, in San Diego. The consensus findings were sent to participants to verify accuracy and permit "fine tuning" before the next meeting. The descriptions which follow are based on drafts obtained from the AEMB. Several sources interviewed for this article stated that "the Committee made some sweeping proposals and we're still looking at the form the new organization will take." Others said that, "there were problems with the way things were written, in terms of what really happened."

There was, however, a consensus supporting the creation of a new infrastructure for bioengineering. Identity was the key element, and everything else—including influence and advocacy—followed. The Steering Committee reported that "there was a feeling that an umbrella organization, e.g., like AEMB or USNCB, would not achieve that key element of identity." The group reported "a wide range of views" relating to the structure, activities and services to be provided by any new organization. The need for constituent society involvement was noted, as was the opinion that identity "could not be achieved" without individual memberships.

Some attendees argued against the establishment of a new organization because a new society "might tend to isolate biomedical engineers and increase tension between a new society and existing engineering societies."

EXAMINING INDIVIDUAL ISSUES

With the rising cost of healthcare and increasing international competition in the medical device industry, many participants were concerned that bioengineers had an important role to play and needed to be a recognized partner in the development of national policies. Some attendees argued against the establishment of a new organization because a new society "might tend to isolate biomedical engineers and increase tension between a new society and existing engineering societies." Concerns were expressed that a new organization might not be financially viable in any case, or that such a group could "misrepresent" the consensus. Others suggested that the number of biomedical engineers might be too small to support another umbrella group. At the same time, a number of participants suggested that the field is too broad to unify. Concern was expressed that a new organization would inevitably lead to redundancy in the services offered to members, assuming the new group accepted individual affiliations as well as those of existing societies. Despite the reservations, a "large majority" agreed on the need for a unifying organization.

The individual working groups categorized their priorities based on the previously described plenary sessions. High priority was given to the need to influence national policy, to enhance research funding, and to facilitate university-industry-government relationships and the proliferation of technical meetings. The groups discussed education and standards regulation as well.

The term "bioengineering" was discussed at length. Widely divergent views were expressed, ranging from those advocating an all-inclusive definition to those supporting an organization composed of "engineering as it applies to human health." There was concurrence that biomedical, bioprocess and biochemical engineers should be included in any event, despite the polarization of opinions.

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The working groups focused on several pragmatic issues relative to the creation of any new organization. They examined structure: board of directors, council, executive committee and staffing. Conclusions could not be reached because there was no consensus regarding the composition of constituent members—groups, individuals, or both. Some participants contrasted and compared a "clump organizational model" with a traditional "society model." They defined the clump model as "an organization composed of many small groups, i.e., 'clumps.'"

Several names were proposed for the new unifying organization, including: Academy of Bioengineering; Academy of Medical and Biological Engineering; National Federation for Bioengineering; and American Institute for Bioengineering. Opinion was divided as to whether "medical" or "bioengineering" was the most unifying word.

Financing is critical to the advent and survival of any organization. Working group discussants envisioned a three- to five-year start-up period during which "lower budgets would be appropriate." Nevertheless, the participants anticipated a steady-state annual budget of $250,000. Attendees addressed the fundamental question: Where will the money come from? If a new organization were to be society-based, income might only reach $25,000 annually with 25 society members. If based on personal affiliation, assuming 2,000 members at $50 per year, income would still meet less than half the expected need. The commenters acknowledged that in any case, a new

society would have to provide substantial "added value" beyond the status quo to successfully attract either professional societies or individual members.

Participants discussed whether or not an annual meeting or conference was appropriate for the hypothetical new organization. Although there was no unanimity, the attendees generally felt that "there should be an annual meeting, but it should not be a technical meeting." Instead, the broad focus should be on national policy, professional issues and continuing education.

DISCUSSION

The results of the present turmoil within clinical and biomedical engineering will take some time to sort out. "People expect things to change," says Yadin David. "I've received letters and calls from all over, from Puerto Rico, Canada, South Africa, too. They all want to be included," he said. As chairman of the Task Force on Clinical Engineering, David is "elated" that the Alliance was "willing to include and accept clinical engineers within the new infrastructure." When asked how that fact would affect the Task Force, he explained that, "We're not putting all our eggs in one basket. The group has really not yet gelled on whether or not to replace the Alliance. If [a hypothetical new umbrella organization] is just a replacement for the Alliance, CEs won't get anything out of it," he indicated. Much will depend on the results of the next AEMB-USNCB workshop in March, 1990.

The **American Society of Hospital Engineering** (ASHE) has other concerns, according to **Thomas Schipper**, C.C.E., chairman of the Clinical/Biomedical Equipment Managers Steering Committee. ASHE will remain

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a member of the Alliance, he stated, although not a participant in the new infrastructure process. "My feeling is that the way they're defining the new group now, it would be detrimental to the field," he said. "It hurts if you solidify job descriptions as opposed to remaining flexible. The field is moving too rapidly for a solid definition." Schipper explained that ASHE's goal is to "help people get the tools to operate in the healthcare workplace." The group has adopted a wait-and-see attitude toward the CE Task Force for similar reasons. Both David and Schipper agree that a lot of informal contact is occurring. None of the organizations interviewed for this article wanted to be categorized as totally in one camp or the other. Rather, each wants to remain abreast of developments. As Schipper put it: "We can't just close our eyes to the world."

AAMI executive director **Michael Miller** also indicates that his organization has not yet taken a formal position regarding the need for a new bioengineering organization or a new society for clinical and biomedical engineers. "No one has concrete data saying that the needs of clinical and biomedical engineers aren't being met," he stated. "By implication, AAMI would say there's no need for a new [clinical engineering] group." Miller noted,

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however, that AAMI is expressing its views on bioengineering at the AEMB-USNCB workshops even though the group withdrew from the Alliance several years ago. He explained that AAMI recently created a *Task Force on Device Research and Healthcare* to investigate whether or not new services and programming are needed. A chairman has not yet been named. Miller expects the Task Force to report in approximately three months, "no later than the May, 1990, AAMI annual meeting." If needs are demonstrated, existing activities would be augmented with "unduplicated new services" as a function of expanding the membership, he said. Neither new programs nor activities have been planned at this point for AAMI's clinical engineers. Miller says that AAMI has reviewed the cost-effectiveness of rejoining the AEMB and has decided not to act at present. He left open the organization's option to rejoin at a later date.

Finding a consensus to describe the course of events discussed within this article has been highly elusive at best. The only agreement in principle derives from participants of the AEMB-USNCB workshop in August, 1989: a new umbrella organization is needed. Beyond that broad statement, little can be said with certainty. The Task Force on Clinical Engineering is pursuing its identity with a mandate stemming from an initial meeting in St. Louis last May and a new agenda formulated in November during a special symposium that occurred as part of the IEEE/EMBS meeting in Seattle. The Steering Committee that arose from the AEMB-USNCB workshop in Washington, DC, last August is similarly pursuing its own broad objectives for bioengineering.

THE ROLE OF THE ENGINEER IN THE HEALTHCARE SYSTEM

The Task Force on Clinical Engineering was more than passingly interested in events surrounding the *11th Annual International Conference* of the IEEE/EMBS meeting in early November. Yadin David chaired a special symposium, *The Role of the Engineer in the Health Care System*, sponsored by the IEEE Health Care Engineering Policy Committee. **John C. Villforth**, of the **Center for**

Devices and Radiological Health, discussed *Innovation, Evaluation and Protection.* **Joseph Bronzino**, Ph.D., of **Trinity College/The Hartford Graduate Center** (Hartford, CT), presented a paper on *Preparation for Advancement of Clinical Engineers in the Hospital Environment.* **Joseph Dyro**, Ph.D., **University Hospital, State University of New York** (Stony Brook, NY) addressed *Issues Facing Clinical Engineers.* **Glenn Rahmoeller** of the **Biometric Research Institute** (Arlington, VA) spoke on *The Engineer Role in the Medical Device Industry.* Yadin David and Gerald Goodman conducted the final talk, *Who Represents the Health Care Engineer?* According to David, EMBS president **Willis Tompkin** attended the event to learn "what EMBS could do for clinical engineers."

Symposium attendees participated in a panel discussion following the formal presentations. "Clinical engineering issues need addressing, but it isn't happening," appeared to be the consensus, David indicated. The Task Force for Clinical Engineering met that night to assess the course of events since the group had last met. They discussed the original AAMI meeting, the AEMB-USNCB workshop and the day's special symposium.

The group discussed an "open letter to hospital administrators" drafted by the EMBS Health Care Engineering Policy Committee. According to David, the "strongly worded" document addresses the committee's concerns regarding how hospital administrators perceive clinical engineers. The Task Force added its acceptance; the document will be published by the IEEE in February, 1990.

A NEW CLINICAL ENGINEERING ORGANIZATION IS PLANNED

The Task Force arrived at an even more important decision in Seattle: the formation of a new clinical engineering organization. The new body will be known as the **North American College of Clinical Engineering**. The Task Force is now developing bylaws, budgets, mission statements and other documents to launch the new organization. "Issues such as geographical location and officers are still in discussion," David said. "We will chart our own mission, independently. If [the new organization] evolves as a program that affiliates with an existing society, so be it," he explained. "In the meantime, let clinical engineers chart their own course." Opinions from other organizations could not be obtained before this article went to press.

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CONCLUSIONS ARE HARD TO COME BY

While "official" positions and recommendations have yet to be adopted by the AEMB-USNCB Steering Committee, the Task Force on Clinical Engineering has certainly seized the opportunity. The groups may or may not continue efforts along parallel paths. Some decisions are expected from the larger bioengineering group after their second workshop in March, 1990. The Task Force is likely to announce further actions over the next few months. Only time will tell if creation of a "North American College of Clinical Engineering" will adequately address the concerns and needs of clinical engineers, biomedical engineers, bioengineers and BMETs across the country. The advent of a "new infrastructure for bioengineers" has yet to occur.

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As always, there are more questions than answers. What will the new clinical engineering college do? How will it relate to existing societies? Who will join? Will a new bioengineering group be formed? The answers to these questions may become more evident during 1990. Until then, each of the respective groups will probably continue the process of discussion that led them to these eventful activities.

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