Title: **Device User Error Reduction (DUER)**, a CDRH outside leveraging project being developed by Chris Parmentier (OSB) and Ron Kaye (OHIP)

Intent: DUER is an initiative to work with and encourage medical device manufacturers to render devices safer by reducing inadvertent use error on the part of device users. DUER is intended to increase awareness of safety issues involving device use, and to foster testing and analysis of medical devices using "human factors" or "user centered design" techniques where safety in the ***use*** of devices is the primary objective.

Problem Presented: There is a considerable amount of error associated with the use of medical devices as attested to by the large numbers of reports FDA receives citing device use error, as well as reports where use error seems to be implied. Researchers in the area of medical device use believe that device use errors are likely to be much more common than errors resulting from mechanical failures. There is also much confusion with respect to where the responsibility for errors with the use of medical devices lies and how to apply efforts to reduce them. Overall, manufacturers of medical devices have expend relatively little effort in this area. It would benefit both the device manufacturing community and users if manufacturers elevate the importance of the issue of errors in the use of their technology. A focus on the perspective of users of technology is a priority that has been well established in other industries such as aviation, power generation, military systems, and the automotive industry. It is difficult and often counter-productive to write specific regulations on many issues related to device use, partly because use issues and device characteristics are constantly changing. The important overall consideration is whether users are able to use a device to perform medical services (for themselves or their patients) without being subject to device characteristics that promote or allow unnecessary errors to occur.

Results:

1. Information gathering and communicating with industry.
    - Presented concept:
        - June, 99 in Oakland to device industry group
        - August, 99 in Denver to representatives of a local industry group
2. Initial interest in participation on the part of some device manufacturers
3. Modification and refinement of the original concept of how DUER might work

What we Learned:

1. Confidentiality issues are different than we thought.
   - We thought that device use error programs might be closely guarded information. It seems that this is not the case, rather the opposite is true; industries want to share information about device use error reduction.
   - Industry representatives want to share information with competitors making similar devices, because "device safety benefits us all and device problems hurt us all"!
   - Sharing information about a company's DUER program is more of an incentive than a disincentive

2. Incentives are important, but often different than we thought
   - Manufacturers are not so interested in a piece of paper (certificate) from FDA, but are interested in other possibilities for the program. If manufacturers don't see meaningful incentives, they won't bother to participate
   - The main incentive for industry to participate in a program such as this is sharing information about DUER with other companies
   - Manufacturers are also interested in access to helpful information from MDR relevant to DUER

3. The incentive of DUER is largely the potential for access to information from manufacturers and FDA on this subject. The DUER project is fundamentally different than the EPA 33/50 outside leveraging program that inspired it in the following ways. (Refer to seminar manual, Appendix 11 and also Appendix 2, for background material about this EPA program.)
   - Device use error does not have a history of specific regulatory action or vocal public interest groups, and there is no system to provide a precise and independent measurement of results.
   - The image of a device manufacturer may be enhanced by undertaking DUER initiatives from the perspective of medical professionals and lay users. However, the extent to which this will occur may be less dramatic than with the EPA 33/50 program and does not currently seem to be the major incentive to manufacturers.
     (Note: to the public, polluting industries are generally seen as "bad" and the EPA as "good." When an industry wins acknowledgement from the EPA, this means a lot to their image. The parallel relationship between FDA, medical device manufacturers, and device users is less well delineated.)

- We can't offer participants reduction in regulation, and providing a written certificate would require consideration of legal issues

Next Steps: 1. Implementation and Development of a DUER web page

- Develop initial application criteria and process (to be brief and easy to implement)
- Identify an initial group of participants for a "pilot" project
- Calibrate acceptance process and criteria
- Refine method of communication with applicants
- Investigate legal issues with kinds of information that can be displayed on the internet on an FDA-sponsored web page
- Discuss any confidentiality issues
- Ensure that the "wrong" message is not sent to manufacturers that are participating (i.e., that the FDA will not question use issues in their products if they participate) or users (i.e., presenting manufacturers with inadequate DUER programs as the "champs" for device use safety.)

Acknowledgment/Incentives

- Explore how FDA will and can acknowledge participants
- Explore further aspects of the program that could serve as incentives or disincentives

Expansion

- Evaluate progress with pilot and prepare for full implementation of national program including outreach activities
- Encourage increased participation
- Refine how program participants and their associated information are acknowledged