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This correspondence addresses the GHTF SG 1 document entitled "Medical Device Classification". I am writing representing the National Electrical Manufacturers Association. NEMA represents manufacturers of medical diagnostic imaging and radiation therapy equipment. Its membership accounts for 95% of the sales in the U.S. NEMA is also aware that AdvaMed is submitting comments to FDA and is in support of those comments.

NEMA's comments address two issues regarding the classification document; (1) the apparent inconsistency between classification rule 10 on page 14 and the decision tree for active devices on page 19, and (2) the inappropriate classification of X-Ray imaging devices into Class C as proposed in classification rule 10.

Inconsistency between classification rule 10 and decision tree

Rule 10 on page 14 states;

"Active devices intended for diagnosis are in Class B:
- if they are intended to supply energy which will be absorbed by the human body, _ _ _
- if they are intended to image *in vivo* distribution of radio-pharmaceuticals."

The first bullet includes ultrasound imaging, MRI and X-Ray imaging. The second bullet includes nuclear cameras for recording images.

The decision tree for active devices on page 19 places all of the above imaging devices into class C.

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NEMA believes that, with the exception of X-Ray devices, classification Rule 10 is correct and that the decision tree which reflects Rule 10 must be corrected, i.e., the 1st and the 2nd exception are to be deleted from the decision tree under Rule 10.

Inappropriate Classification of X-Ray Imaging Devices in Class C

NEMA believes all diagnostic imaging devices should be classified in class B. To cull out X-Ray imaging devices for class C simply because they emit ionizing radiation is not appropriate.

The bioeffects of ionizing radiation are well understood, and have been well understood for many years. Most diagnostic imaging devices produce energy that is absorbed by the patient; so why cull out X-Ray imaging devices based on their emitting ionizing radiation.

The benefit of producing X-Ray images has far outweighed the risks from the exposure to ionizing radiation during diagnostic procedures. As with other imaging devices, there are international and national standards in place for X-Ray imaging devices and manufacturers have been building equipment to these standards for many years. Adherence to these standards, improved collimation of the X-Ray beam and improved efficiency of image receptors over the years has resulted in reduced patient exposure to ionizing radiation. The medical profession has accepted the occupational and patient risks from ionizing radiation as an absolute necessity for producing the life enhancing and life saving images this equipment has to offer.

If the classification of X-Ray imaging devices is based solely on their emitting ionizing radiation, to place them in the same class as radiation therapy devices is completely inappropriate.

Radiation therapy devices deliver ionizing radiation per procedure many orders of magnitude greater than X-Ray imaging devices. NEMA believes strongly that Class B is sufficient for all diagnostic imaging devices including X-Ray imaging devices. Therefore, the last paragraph in rule 10 should be deleted, as well as the last exception from the decision tree under Rule 10.

SUMMARY OF CHANGES

I. Suggested changes to Classification Rules

- added one sub-sentence for clarity (PS. Note that lamps are not really "active devices intended for diagnosis"; perhaps this exception could be deleted. If not, then the exception should also show up in the decision tree under Rule 10);
- suggested changes for clarity in the 3rd dash
- deleted the last paragraph, where diagnostic radiology equipment was made class C

10. Active devices intended for diagnosis are in Class B: - if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum, in which case they are in Class A, - if they are intended to image *in vivo* distribution of radiopharmaceuticals, - if they are intended to allow direct diagnosis or monitoring of ~~vital~~ physiological processes, unless they are specifically intended for monitoring of those vital physiological parameters, where the nature of variations in output values is such that ~~it could result in~~ immediate danger to the patient could arise, ~~for instance variations in~~ such as cardiac performance, respiration, activity of CNS in critical situations, in which case they are in Class C. ~~Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class C.~~	These are active devices intended for diagnosis. They include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.

II. Suggested changes to Active Devices Decision Tree, Rule 10, Active diagnostic devices

Eliminate all class C decisions with the exception of "when used to monitor/diagnose vital processes where variations could result in immediate danger."

Sincerely

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