

From: "Dimmick, Lisa" <lisa.dimmick@us.nucletron.com>
To: "Barbara Park" <bpark@mde.state.md.us>
Date: 6/11/2007 11:12:48 AM
Subject: RE: SS&D

Only delete "Alpha, Beta, Gamma format"

-----Original Message-----

From: Barbara Park [mailto:bpark@mde.state.md.us]
Sent: Monday, June 11, 2007 10:13 AM
To: Dimmick, Lisa
Subject: RE: SS&D

Why does he want all that deleted? I will check back at my rationale.

b

>>> "Dimmick, Lisa" <lisa.dimmick@us.nucletron.com> 06/11/07 9:51 AM
>>>

Hi Babara,

Interluminal and intraluminal were used in the sheet. I did the same rationalization-- inter versus intra for the "lumen." But, I think you are right with interluminal. Thanks for verifying.

The correction Leo sent was on page 5 under Prototype Testing and it is just a deletion for clarification purposes.

"...The device was developed under ISO 9001:2000 and EN ISO 13485:2003 (KEMA certificate #55859) Quality Systems Requirements. The manufacturer indicates that the prototype was tested to conform to design specifications and that functional and safety aspects of the system (Alpha, Beta, Gamma format) were checked under normal and single fault conditions. New software for the device was tested and passed under the manufacturer's Treatment Console Software Test-Plan..."

Lisa

-----Original Message-----

From: Barbara Park [mailto:bpark@mde.state.md.us]
Sent: Monday, June 11, 2007 9:40 AM

From: "Dimmick, Lisa" <lisa.dimmick@us.nucletron.com>
To: "Barbara Park" <bpark@mde.state.md.us>
Date: 6/11/2007 9:52:26 AM
Subject: RE: SS&D

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Lisa

-----Original Message-----

From: Barbara Park [mailto:bpark@mde.state.md.us]
Sent: Monday, June 11, 2007 9:40 AM
To: Dimmick, Lisa
Subject: Re: SS&D

Yes I got it, unzipped it and am working on it.

I have contention with the words interluminal vs intraluminal. This is on page 4 under d. Inter would mean within the lumen and intra would mean between lumens (luminae). I would think it would be inter and I think it is that way on other sheets but I have just gotten there to

that point and have not checked.

Yes, just send page number, etc. Also, I am primary reviewer and Ray is concurrence, just fyi--I am reversing that at the end page.

b

>>> "Dimmick, Lisa" <lisa.dimmick@us.nucletron.com> 06/11/07 9:25 AM

>>>

Hi Barbara,

I was just checking if you received the draft SS&D last Friday. I

tried

a couple times but the word file was too large and exceeded you e-mail

sized limit -at least that is what the failure notice indicated. My

husband did zip it and re-sent it late Friday afternoon. Let me know

if

you received it and it opened OK. I have one other minor correction

that Leo sent to me that I will forward shortly. If you received the

file last week, then I'll just let you know the page and line # for

the

new correction.

Thanks,

Lisa

Lisa Dimmick

Director of QA& RA, RSO

Nucletron Corporation

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Mobile: +1 (443) 253 9172

lisa.dimmick@us.nucletron.com

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copy
of it from your computer system. Thank you.

<<<<GWIASIG 0.07>>>>

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