**UNCONFIRMED MINUTES**

**MAY 6, 2014**

**CINCINNATI, OHIO, USA**

**These minutes are not final until confirmed by the MedAccred Management Council in writing or by vote at a subsequent meeting. Information herein does not constitute a communication or recommendation from the MedAccred Management Council and shall not be considered as such by any agency.**

**TUESDAY, MAY 6, 2014**

# OPENING ADDRESS and welcome

## Call to Order

The MedAccred Management Council (MMC) was called to order at 8:30 a.m., 06-May-2014.

The following representatives in attendance:

***Subscriber Participants Present***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | NAME |  | COMPANY NAME |  |
|  |  |  |  |  |
|  | Denise | Caldwell | Philips Respironics |  |
|  | Elisabeth | George | Philips Healthcare |  |
|  | Ravi | Nabar | Philips Healthcare |  |

***Other Participants Present***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | NAME |  | COMPANY NAME |  |
|  |  |  |  |  |
|  | Jim | Ahle | Stryker |  |
|  | William | Davis | Lake City Heat Treating Corporation |  |
|  | Jennifer | Doubet | Boston Scientific |  |
|  | Edward | Engelhard | Solar Atmospheres Inc. |  |
|  | Ed | Engelhard | Solar Atmospheres | Via Teleconference |
|  | Vance | Kyle | DePuy | Via Teleconference |
|  | Steven | Niedelman | King & Spalding |  |
|  | Dan | Solowy | Global Technologies |  |
|  | Ken | Stopar | Baxter Healthcare |  |

***PRI Staff Present***

|  |  |
| --- | --- |
| Bekah | Gondek |
| Michael | Graham |
| Kellie | O’Connor |
| Joe | Pinto |

## Anti-trust and Code of Ethics

Joe Pinto reviewed the Anti-trust and Code of Ethics policy, and attendees reviewed a short video. For more information, please see the attached presentation.



Bekah Gondek noted that the badges have different identifiers for levels of participation. For those in the room, blue badges were given to MedAccred Subscribers, orange badges were given to all non-subscriber participants, and green badges were given to PRI Staff.

# MMC Sub-Team Activities: Recap and Discussion



## Program Documents

## PD1300 has been formed from existing Nadcap program documents. Following revisions to bring the document in line with MedAccred, it was sent to all participants for review and comment.

## External Communications and Strategy

This is the most active of the MMC Sub-Teams, with all activities intended to educate industry participants on the program. For more information on recent and future activities of this team, please see the embedded presentation above.

It was mentioned that AdvaMed, which will take place in Chicago from October 6-8, 2014, would potentially be a good audience for a MedAccred presentation. It could provide some good opportunities for more involvement and participation from additional industry participants. It was noted that several of the companies which are being pursued for MedAccred participation are also part of AdvaMed, reaffirming the potential benefits of attending this conference.

There was additional discussion regarding MD&M West, as it is the largest of the MD&M conferences. Joe Pinto noted that the real value would be found in booking a booth, as the target audience is the people walking the floor. This item will be discussed amongst the External Communication & Strategy Sub-Team, which will look into possibly getting a booth for the next MD&M West.

# TASk group activities



## Electronics – Printed Circuit Board Assemblies (PCBA)

The Task Group is meeting regularly, with good representation. The PCBA checklist is mostly complete, and the group is working to reorder the questions to provide a better, more consistent pathway for the audit, in alignment with how the process takes place.

It was noted that although a list of suppliers were provided for this particular group by various OEMs, there hasn’t been much additional supplier activity as a result.

There was a discussion about next steps to move from Proof of Concept to accreditation audits. Checklists must be made available to the applicable suppliers and self-assessments must be conducted. It will likely take 3-6 months to allow suppliers to properly prepare for an actual accreditation audit. The group was reminded that there is also a possibility of creating an eQuaLearn course to assist suppliers in their audit preparation, with topics such as: How to Conduct an Internal Audit; MedAccred Audit Preparation; Pyrometry; and Root Cause Corrective Action (RCCA).

Jim Ahle recommended that we add a section to the Task Group Update slides reflecting how long it will be until the checklist are ready to be used in accreditation audits. Another idea may be to create a “process flow” with next steps and available resources to help suppliers prepare for an audit.

ACTION ITEM: PRI Staff to add expected completion date of checklists to TG Update slides as well as when they contract their 1st and subsequent auditors (Due Date: on-going, next MMC Call)

## Electronics – Cable & Harness (C&H)

The C&H Task Group have been able to use and incorporate many of the changes made to the PCBA checklist. Work and review of the checklist continues, and it is expected that the checklist will probably be finished within the next 3 months.

## Heat Treating

There is a scheduled teleconference call today with a new supplier who has expressed interest in getting involved. A Task Group Chairperson has been elected, Bruce Dall from Stryker. The group has finalized the baseline checklist, which will go to formal ballot the week of May 5, 2014, for a period of 28 days. Work has also begun on slash sheets, which will contain questions for the different associated processes for Heat Treating. The current plan for 2014 is to perform 10 audits. Marcel Cuperman noted that many of the current supplier participants already have Nadcap accreditation for aerospace, which will hopefully reduce the amount of time needed to prepare for a MedAccred audit. The Task Group has suggested standardizing Process Validation across the MedAccred program, as different OEMs have different parameters for the suppliers.

There was some concern from OEMs about standardizing Process Validation. Further thought and discussion is needed before committing to standardization.

## Sterilization

There are currently 8 active participants, however no supplier support as of yet. The Task Group, who previously elected Cheryl Work as Chairperson, has selected a Vice Chair, Donna Gallagher from Stryker. The group is now working to develop ethyleneoxide and radiation slash sheet checklists. The base checklist is mostly finished.

The Sterilization Task Group will be having their first face-to-face meeting May 13-14, 2014 at the Stryker facility in Malvern, Pennsylvania. Mark Aubele asked for additional support for participation in the meeting. There was some concern that there hasn’t been any support from the Sterilization supplier community, as we need some of the expertise. Steve Niedelman offered to approach some members of that community during the MedCon conference this week and ask if they would be willing to participate.

## Welding

The Welding Task Group is continuing to work through the checklists, and there are currently only 2-3 outstanding items left for resolution. The supplier who participates on the group may potentially do a pilot audit and the group is hoping to send checklists to formal ballot by end of month. Additionally, there are some auditors that they will be interviewing with hopes that at least one will be approved.

The group will also be working on handbooks as guidance for the checklists. Once again, the Task Group has discussed the need for a Nondestructive Testing (NDT) task group. For the time being, the requirements have been incorporated into the Welding checklist, however they really should be done by an NDT group. He also mentioned that the majority of Welding suppliers do not have the existing necessary quality system certification, so there may be an increased need for a potential AC8004, which would be a MedAccred quality system checklist.

# Minimum Quality System Requirements for Suppliers receiving MedAccred Accreditation

## The MMC reviewed Task Group feedback in regards to which registered Quality Management Systems are necessary for that commodity. For more details, please see the embedded presentation.

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The MMC discussed what the minimum requirement should be and also what should be defined as acceptable in the program documents. There was discussion regarding ISO 13485 and how much of it does not apply to Medical Device suppliers. It was suggested that perhaps the minimum could be ISO 9000, with perhaps 1 or 2 alternatives. At that point, if a given supplier did have ISO 13485, they would be over and above what is considered acceptable.

The general consensus was that having a mechanism such as an AC8004 would help cover the spectrum of Medical Device suppliers. This would be a particularly good avenue for niche suppliers who cannot afford to get ISO 13485.

It was noted that the group may want to consider adding the automotive equivalent of AS9100, TS 16949 to the list of acceptable quality systems. Elisabeth George suggested creating an Excel matrix of the quality standard requirements, to ensure that all relevant requirements are covered in each, which will help to establish a minimum.

ACTION ITEM: Create a matrix of quality systems listing all requirements to analyze if it’s worthwhile to create an 8004 checklist. (Team: Ken Stopar, Pete Kucan-staff lead, Paul Mehta, Steve Niedelman) (Due Date: On-going, with monthly updates)

ACTION ITEM: PRI Staff to ask all Task Groups if they are willing to accept applicable sections of all the quality systems on the list, including the newly added TS16949, and are they willing to accept an AC8004, if created. (Due Date: Pending completion of above action)

William Davis mentioned that he also does Nadcap and has the Nadcap Aerospace Quality System AC7004. He asked if he would then need to have two quality systems audits, an AC7004 as well as an AC8004? If the 8004 is created and accepted, MMC will need to conduct a gap analysis with 7004 to ensure that the minimum requirements are covered for the needs of the Medical Device community.

# Program Governing Document - PD1300

A high level overview of PD1300 was given, which defines the scope of the program, critical manufacturing processes, participation levels, roles/responsibilities of participants.

# Mandating MedAccred accreditation

## Bekah reviewed what it means to mandate MedAccred to the supply base. For more details, please see the attached presentation.



## Each OEM will need to discuss how they will use MedAccred internally and what critical processes should be addressed and in what order. Timing of mandates is very critical, as suppliers will need adequate time to prepare for an audit. OEMs will need to evaluate which of their suppliers will be mandated to MedAccred accreditation.

Joe Pinto emphasized the importance of OEMs sharing their supplier lists. It will not only help with communicating checklists when they are ready, but additionally there are a number of tools and metrics in place within the eAuditNet system which can help the OEMs keep track of and manage their suppliers.

Jim Ahle detailed his intended roll-out of MedAccred to the supply base, mentioning that he would need to get MedAccred into the purchasing control system. Initially, the most likely approach will be to require any new suppliers to be MedAccred accredited. Further down the road they will roll it out to existing suppliers. The driver for a lot of OEMs is the ability of MedAccred to get to the heart of the actual process, and eliminate escape defects.

Instead of using the word “mandate”, there was discussion that perhaps a better approach would be to use the word “encourage”. Possible incentives for suppliers to become accredited will be placement on a preferred supplier list. It was suggested that perhaps some of the different examples of Nadcap mandate letters be reviewed in order to develop a form letter for MedAccred. Another method of encouragement could be to ask a Nadcap user to attend one of the promotional events where MedAccred will have a presence, where they could speak to the benefits of this accreditation program and particularly how Nadcap has positively affected the aerospace industry. It was agreed that a Nadcap-accredited supplier’s experience could have a lot of impact on the Medical Device supplier community.

ACTION ITEM: PRI to gather testimonials about increased business and improved process & quality from Nadcap accredited suppliers who are involved with Medical Devices (Due Date: 31-Jul-2014)

Once the finished checklist is posted in eAuditNet, MedAccred will need to communicate to Suppliers and OEMs, emphasizing the importance of registering in eAuditNet. This is what will give them access to the checklists. Once the checklists are accessible, some potential ideas for educating the supply base are: conducting pre-assessment audits (a PRI-conducted Gap analysis for a fee); OEMs visiting key suppliers to educate them about those key processes – support gap analysis to compare their process vs. MedAccred checklists; Supplier Symposia (conducted by PRI, OEMs, and Nadcap/MedAccred Suppliers).

There was discussion on whether to hold a MedAccred meeting back-to-back with a Nadcap Meeting to allow for Nadcap participants to attend and discuss the value of the program. Due to the timing and logistics of a Nadcap Meeting, this may not be beneficial; however a presentation to the Nadcap Supplier Support Committee (SSC) may provide some benefit.

ACTION ITEM: Joe Pinto to discuss the MedAccred program during the next Nadcap SSC Meeting. (Due Date: 21-Oct-2014)

ACTION ITEM: PRI Staff to investigate what trade associations exist, particularly in the areas which MedAccred is currently focusing. (Due Date: 10-Jul-2014)

There was discussion about down the road having a joint audit for Nadcap and MedAccred, for those suppliers who do both. If this becomes a viable option, the audit would be conducted by an auditor who is qualified by both the Nadcap Task Group as well as the MedAccred Task Group.

There was further discussion regarding Process Validation and whether it should be handled at a Task Group level or standardized at an MMC level. There is a difference between validating the process and qualifying the part. Validation is 1) equipment qualification 2) is the iq/oq and pq done. When a Nadcap/MedAccred auditor goes to a facility, that check is critical to everything coming out of that line. The Nadcap/MedAccred process will make the part validation process much easier, because there is an assumption of Supplier capability and process capability. If those two things have been verified, the part validation, in theory becomes easier.

# Subscribing to MedAccred and Gaining Voting Membership



The current structure of MedAccred Subscriptions and Voting Membership were reviewed and discussed. There is one level of Subscriber, however the amount of access and also cost can be adjusted for contract manufacturers, who would only have access to their own information. All Subscribers would have a voice, however. Elisabeth George suggested adopting a similar structure to MDMA for fees, voting, etc., which has five levels of membership, with fees differing depending on which membership level is held.

ACTION ITEM: Program Document sub-team to redefine future rules of engagement for all participants in the MedAccred program (including small OEMs into the program) and evaluate associated voting rights and cost structure. (Due Date: 31-Dec-2014)

# MedAccred Program Leadership



Leadership positions of the MMC are Chairperson, Vice Chairperson and Secretary and may be held by Subscriber Voting Members.

Once a Supplier Support Committee is established, those Leadership roles would be held by Supplier Voting Members.

It was mentioned that the Nadcap program will be conducting a Chairperson training at the upcoming June 2014 Nadcap meeting in Dublin. It may be a good idea for the MedAccred participants to undergo this training as well to familiarize everyone with Task Group leadership and structure.

It was also noted that a Program Governing Board will sit above the MMC and will be limited to 7 participants of senior management. They will have financial responsibility of the program, oversee activities of MMC, determine what metrics will be reported, and will report on MedAccred to the PRI Board of Directors.

# Other Business and Open Discussion

## There was discussion about the NUCAP program and how it could potentially apply to the MedAccred program, with auditing of internal suppliers. It was noted that the difference between NUCAP and Nadcap is two-fold: 1) The OEM’s data and audit information is not available to the entire Task Group, it is only available to them, and 2) There is the availability of a scope extension, which allows the OEM 12 months to either correct a particular issue, or to address the applicability of that requirement with the Task Group.

## There was a question about when other Task Groups / processes will be started up. Joe mentioned that at the moment, it is difficult to start up additional Task Groups from a resource perspective, as well as to ensure that we can get the program started and off the ground. There was a suggestion to conduct a poll to find additional areas of interest to ensure that OEMs can support, because an OEM is more likely to sign up and subscribe if the right processes are being offered, such as plastics and batteries.

ACTION ITEM: PRI Staff and External Communication & Strategy Sub-Team to bring forward discussion on strategy for adding new task groups to the MedAccred program (Due Date: 31-Oct-2014)

## There was a question as to whether there were references to international standards in any of the documents being developed. The answer is yes, all Task Group checklist requirements are linked back to an industry standard or collective OEM requirements. It was requested that PRI consider adding references from standards as a required activity by the Task Groups. This exists in Nadcap procedures, however has not yet been added to MedAccred. It was agreed that this should potentially be added to PD1300 as part of a Task Group responsibility. It was also suggested that a process be created to add necessary standards to the FDA list of approved standards.

ACTION ITEM: Heat Treating Task group, with support from Elisabeth George, to take the AMS2750 to FDA for addition to the list of approved standards. (Due Date: 30-Jun-2014)

# Rolling Action Item List (RAIL) Review

All actions from this meeting were reviewed.

ADJOURNMENT – 06-May-2014 – Meeting was adjourned at 4:30 p.m.

Minutes Prepared by: Kellie O’Connor, koconnor@p-r-i.org

RAIL:

